GE Healthcare

Diamond

Operation Instructions

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86500-IMG rev 3

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This manual applies to Diamond units with software version 1.02.5 and up.

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1 Introduction

1.1 General information

Diamond is a high quality X-ray breast imaging system intended for both screening and diagnostic examinations. Its main features are the *AutoPoint* Detector, *ParkBack* tube head, motorized C-Arm rotation, *ECS*-(Easy Compression System) movement, stereotactic option, digital-ready design, rotating dual-angle anode tube, *ROC* grid option, Tuned High Frequency (*THF*)-generator and its easy positioning of the patient.

The height adjustment is motorized, and the motorized C-Arm rotation range is ±185° degrees. Motorized compression of the breast is controlled by compression foot pedals, and the manual compression by manual compression wheels. If necessary, the compression can be released automatically after exposure. In the event of power failure, the compression is released automatically.

The THF generator is integrated into the unit saving space in the mammography room. The exposure button is located on the compact control panel.

All functions of the unit are controlled by a microprocessor, and the operator is informed of error conditions on the control panel display. The Diamond incorporates many safety features, for example, exposures without a cassette installed or double exposure are prevented.

The Diamond is intended only for mammography examinations, no other uses are permitted. Both film sizes, 18 x 24 and 24 x 30 can be used. Diamond is intended to be installed for stationary use. If a mobile van installation is necessary, please contact II to check for the availability of a special van kit.

NOTE!

Move the foot pedals away from the working area to prevent any unwanted activations of compression.

WARNING!

Never use the equipment if it is suspected that any electrical, or radiation-emitting component is defective or inoperative.

WARNING!

Only trained, licensed persons are allowed to operate the Diamond unit.

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WARNING!

USE LIMITATION : External components: The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of the EQUIPMENT and/or SYSTEM.

WARNING!

If you suspect any electro-magnetical interference affecting or caused by the unit, call service. Portable and mobile RF communications equipment can interfere with operation of the medical electrical equipment.

GE accepts no responsibility for safety, reliability or performance unless:

- Assembly, calibration and repairs are performed by an GE-authorized representative according to the corresponding Diamond manuals.
- Any modification, addition or deletion to this system is authorized specifically by GE, in writing.
- Electrical installation complies with the IEC regulations.
- The system is used in accordance with the Operating Instructions.

Each Diamond unit has been tested for leakage radiation and the test results are recorded in the final test protocol.

This device emits X-ray radiation for medical purposes. The Diamond X-ray tube has a Molybdenum anode. X-rays are either Molybdenum-, Rhodium- or Aluminum-filtered. The Minimum HVL is 0.3 mm Al@30kV tube voltage without the compression paddle. Diamond is CE-marked in accordance with MDD (93/42/EEC) and its design complies with IEC 60601-1. Diamond fulfills the EMC requirements of IEC 60601-1-2 2.ed. The Diamond breast imaging unit is tested and certified according to UL/ CSA.

1.2 RADIATION PROTECTION

As radiation is harmful to the human body, the radiation protection regulations of individual countries must be complied with. The user must have permission to use an x-ray device for mammography. Radiation protection means should be used. Prior to examination, it is recommended to make sure that the doctor knows if the patient is pregnant. If someone has to be close to the patient, protective clothing must be used.

The optional **radiation shield** must be used, or the unit must be operated from a shielded control room (significant zone of occupancy is 2 meters). During the exposure, visual and audible contact should be maintained with the patient. The free-standing radiation shield can be positioned as required in the X-ray room. An mammography accessory storage unit is available as an option and may be placed behind the free-standing radiation shield. Diamond with radiation protection is in accordance with IEC 601-1-3:1994.

Fig 1.1. Optional radiation shield (34135-IMG)

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CAUTION!

The maximum radiation that the system is capable of producing corresponds to 5% of the typical CT-radiographic exposure. However, the user should wear a dose-recording device and follow local regulations for radiation protection.

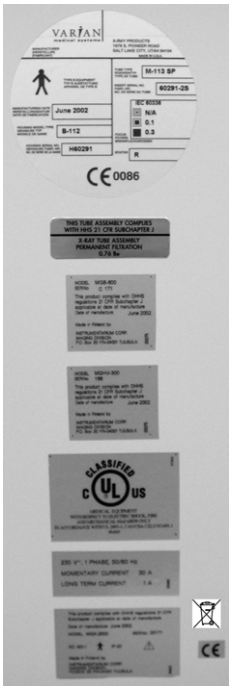

Fig 1.2. Labels at the back of the column

1.3 SERIAL NUMBER AND YEAR OF MANUFACTURE

Device serial number, year of manufacture and some other labels are located at the back of the Diamond column.

1.4 MARKINGS IN THE MANUAL

The manual may have the following markings:

NOTE!

Contains useful information for the reader about the unit and its usage.

CAUTION!

Contains important instructions. If these instructions are not observed, malfunction of the unit or damage to the unit or other property may occur.

WARNING!

Contains warnings and instructions about the safety of the unit. If these warnings are not respected, risks and injury may be caused to the patient or operator.

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2 Operating controls

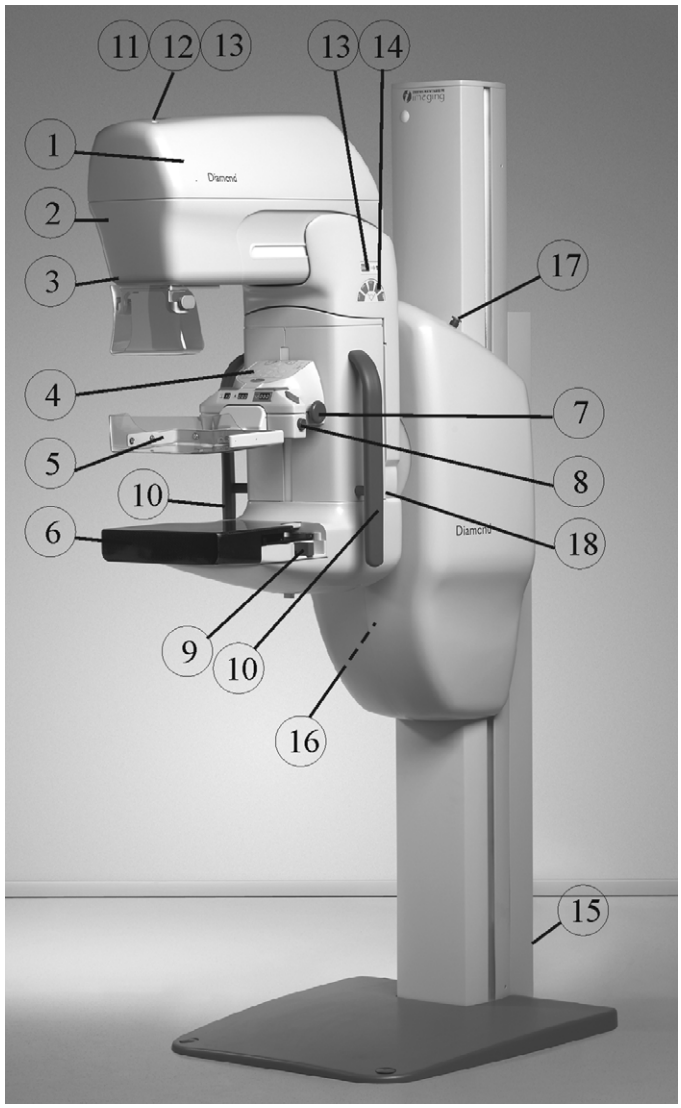

Fig 2.1. The stand

1	X-ray tube	10	Patient hand grip
2	Diaphragm/collimator	11	C-Arm rotation buttons
3	Face shield	12	Vertical movement buttons
4	Position Control Center control buttons (refer to Figure 2.4)	13	ParkBack control buttons
5	Compression paddle	14	Pre-programmable C-Arm angle buttons
6	Cassette holder	15	Mains switch (automatic trip switch at the rear)
7	Manual compression wheels	16	User power On/Off switch
8	Compression paddle release button	17	Emergency stop buttons, one on each side
9	Cassette release button	18	Tube head stereoangulation buttons

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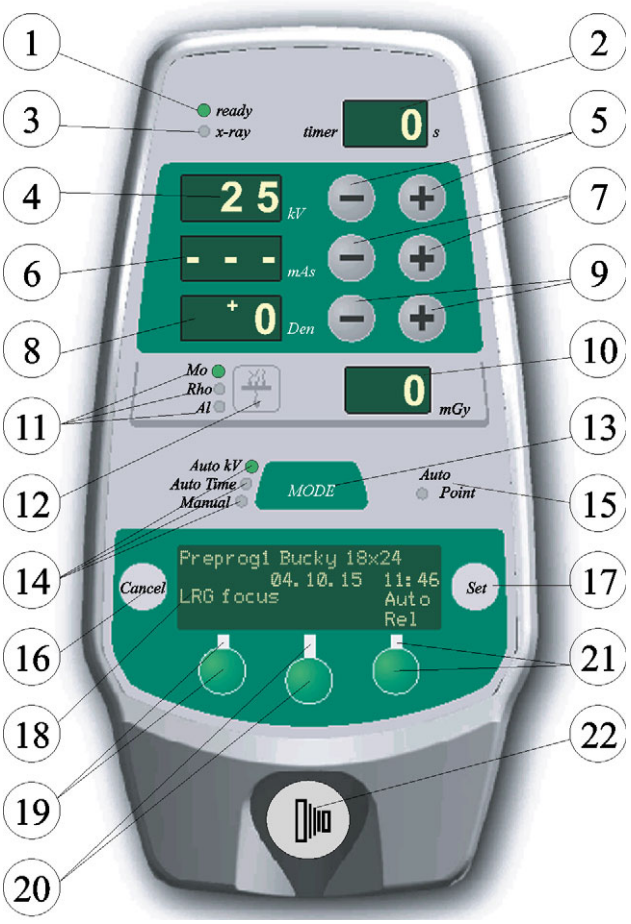

Fig 2.2. Control panel

1	Ready indicator, green	12	Filter selection button
2	Exposure time display	13	Mode selector for Auto-kV, Auto Time and Manual
3	Radiation indicator, yellow	14	Phototimer mode indicators, all green
4	kV display	15	Auto point indicator, green
5	kV selection	16	Cancel button for menu operations
6	mAs display	17	Menu and Set button for menu operations
7	mAs selection	18	LCD display
8	Density display	19	Function key 1 and LED indicator
9	Density selection	20	Function key 2 and LED indicator
10	Average glandular dose display	21	Function key 3 and LED indicator
11	Filter indicators, all green	22	Exposure button

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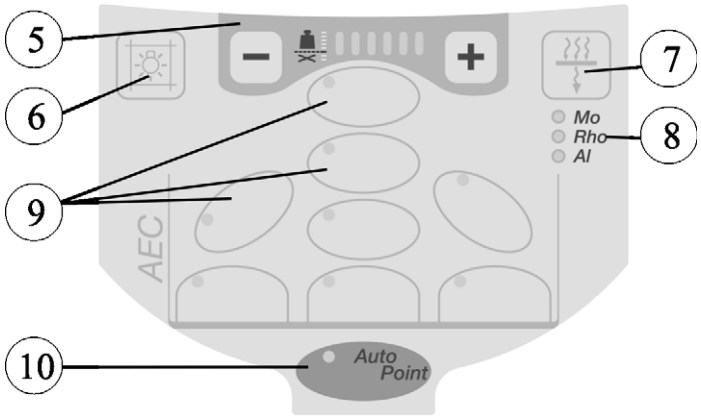

Fig 2.3. The Positioning Control Center panel membrane

1	Compression paddle release button	8	Filter selection display
2	Manual compression wheel	9	AEC detector selector buttons
3	C-Arm rotation buttons	10	AutoPoint detector button and LED indicator
4	Vertical movement buttons	11	Breast thickness display
5	Compression force control (1-6)	12	Compression force display
6	Collimator light switch	13	C-Arm rotation display
7	Filter selection button		

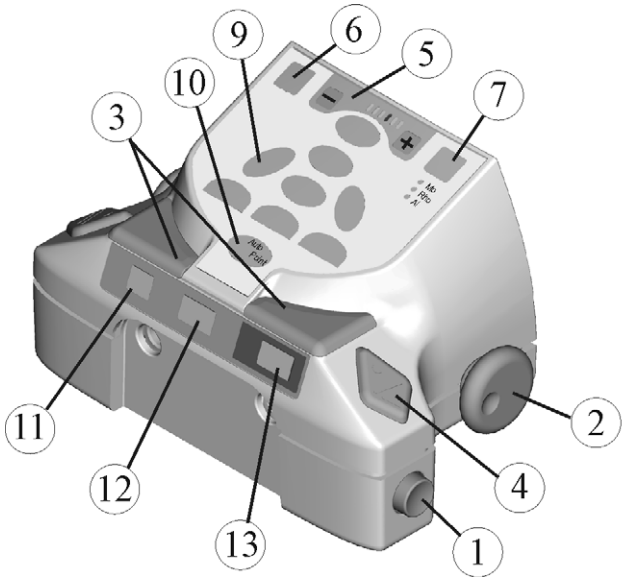

Fig 2.4. Position Control Center controls

Fig 2.5. A: Breast thickness display (cm), B: Compression force display (N),C: C-Arm rotation display (°)

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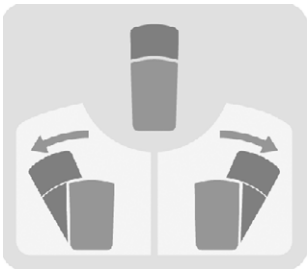

Fig 2.6. Tube head stereo angulation buttons

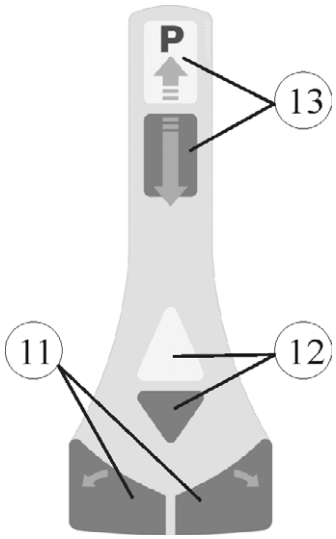

Fig 2.7. Top down: The tube head cover with C-Arm rotation buttons (11), Vertical movement buttons (12) and ParkBack buttons (13).

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3 Preparations for operation

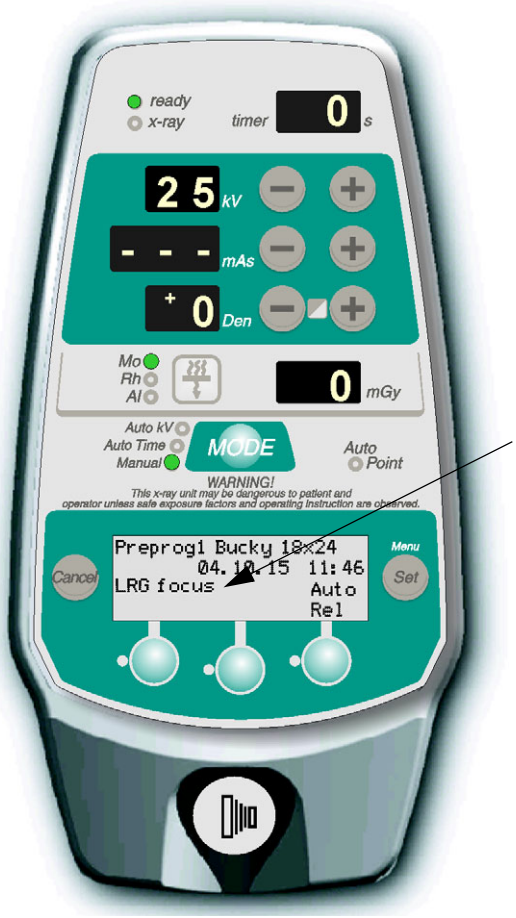
3.1 PRECAUTIONARY ACTIONS FOR SAFE USE

Make sure that the siting of the unit allows unobstructed rotation of the C-Arm and that it will not strike any object throughout its full movement range. Please also take care to ensure that the user does not place her/his self in-between the C-Arm and any nearby object when attempting to rotate the C-Arm, as injury could result.

Make also sure that the foot pedals are located so that the patient will not accidentally operate them during positioning and imaging procedures.

3.2 SWITCHING ON THE UNIT

Make sure that the mains switch is on. Then switch ON the mains power with the user power ON/OFF switch. The following will appear on the on control panel display screen (with factory defaults dependent upon the final installation configuration):



When LRG focus is displayed, large focus is selected.

When SML focus is displayed, small focus is selected.

Fig 3.1. Diamond Control Panel default screen

The timer display now shows **0**, kV display 25, mAs display - - -, density display **+0** and mGy display **0**. Auto-kV is a factory default setting. Your GE-approved service technician can change the default setting if required.

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Switching ON and OFF restores the default settings on the control panel. It is recommended that you allow a warm-up period of approximately 3 minutes after the unit is switched on.

3.3 CONTROL PANEL

Diamond's control panel uses an LCD-display and 7-segment LED displays for status information display and has various buttons to regulate the functions of the X-ray unit.

The control panel can be attached to the radiation shield or to the wall. Exposure can be initiated only from the control panel exposure button. Use of the function buttons depends on the menu display and required functions. These buttons are used to choose various imaging modes, to select the Integrated Quality Control (IQC) function and date, time and hospital information input.

Use the Cancel button to go back one step in the menu without selecting an option or to cancel a selection. Use the SET button to accept selections and to proceed to the next step in the menu. The exposure button initiates the exposure signal to the computer, but when it is released, the hardware inhibits the exposure. The use of the LCD-display and control panel interface in service and setup modes speeds up the installation and service.

3.4 ACCESSORIES

A usual Diamond unit delivery includes:

- Diamond unit
- Buckies and paddles according to order
- Two foot pedals
- Control panel
- Operating instructions

The following accessories are available for the unit (refer to Diamond Accessory Catalog (86503-IMG) for complete listing of accessories and order codes). Choose the accessories necessary to your procedures:

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NOTE!

All accessories that the Diamond manufacturer supplies for Diamond are suitable within the patient environment, unless otherwise indicated.

3.4.1 Compression paddles

21x24 cm compression paddle

The 21x24 cm compression paddle is the standard paddle used with the 18x24 cm film format when using the Bucky.

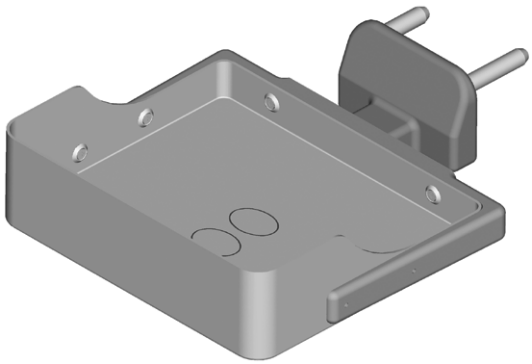

Fig 3.2. 21x24 cm compression paddle

Usually, this paddle is used with 18x24 cm film and should not be used with the 24x30 cm film and the corresponding Buckies, because it does not apply compression to the whole breast being imaged, especially to the upper quadrant of the breast in oblique and lateral views. However, it can be used to examine women who have a long breast to shoulder distance.

24x30 cm compression paddle

The 24x30 cm compression paddle is used with the 24x30cm Bucky.

It applies compression to the whole breast area being imaged.

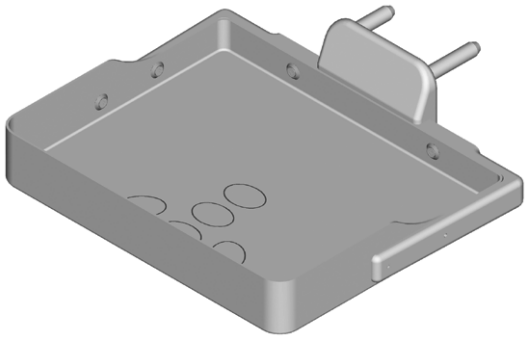

Fig 3.3. 24x30 cm compression paddle

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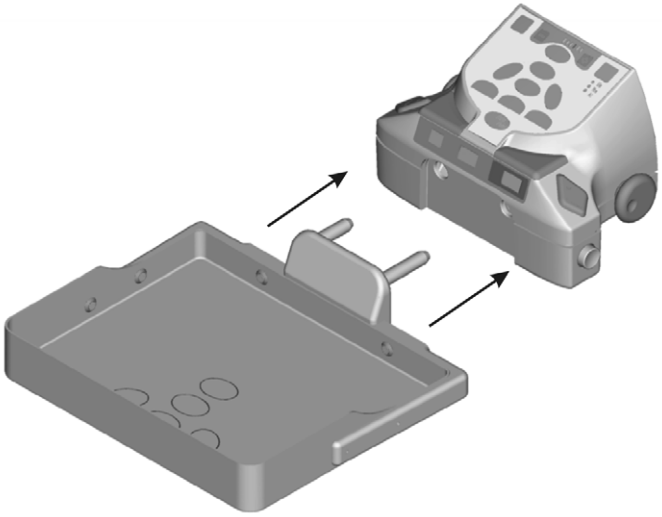
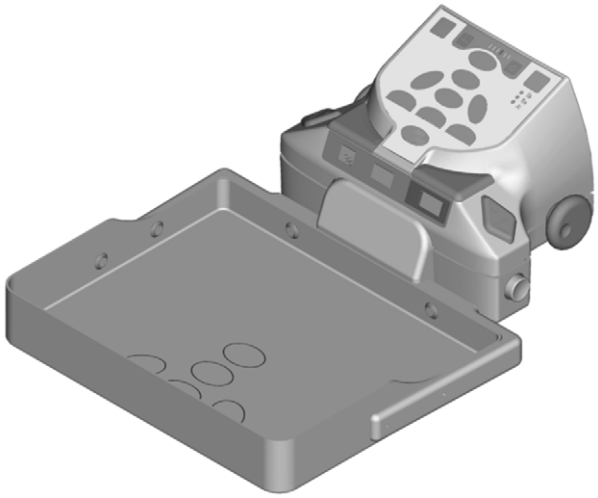
3.4.2 Insertion and removal of compression paddles

3.4.2.1 Insertion

1 Insert the required paddle into the holes on the compression arm and push the paddle horizontally until it locks. Insert the paddle so that the longer pin of the two slides into the right-hand hole.



2 The inserted compression paddle looks like this.



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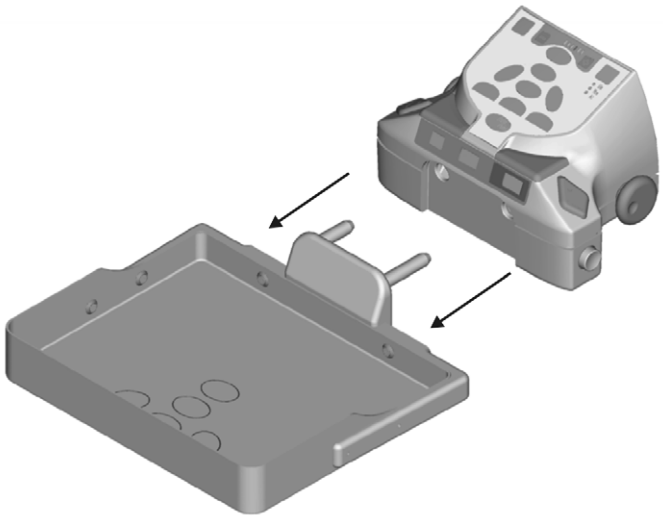
Removal

1 Push only one of the release buttons (7) located on both sides.

2 Remove the compression paddle by pulling it out horizontally.



3.4.3 Cassette holders

The following Bucky types are available for mammography examinations with Diamond. Refer to Diamond Accessory Catalog (86503-IMG) for complete listing of Buckies and order codes.

- Synchro Bucky 18x24cm or ROC Synchro Bucky 18x24cm
- Synchro Bucky 24x30cm or ROC Synchro Bucky 24x30cm
- Multichoice magnification tunnel (one holder for magnification factors 1.6x, 1.8x and 2.0x)

Diamond Buckies are configured for daylight (DIN) cassette use.

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Bucky

The Bucky is the most often used cassette holder in mammography. It has a moving grid inside, which is used to reduce the amount of scattered radiation reaching the film. Primary radiation goes directly through the breast and the grid and produces the image of the breast on the film.

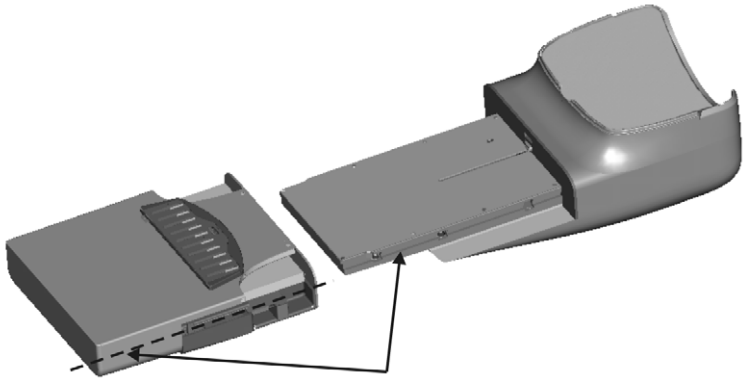
Scatter radiation has an arbitrary angle and thus produces no image on the film but only reduces the contrast in the final image.

Separate Buckies are available for both 18x24cm and 24x30cm film formats.

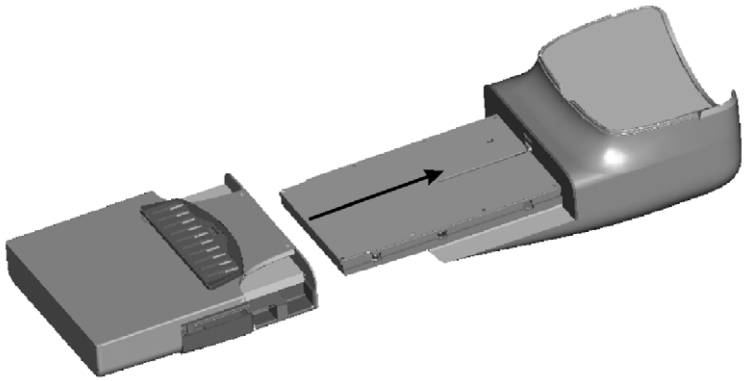
3.4.4 Insertion and removal of Buckies

Insertion of the Bucky

1 Align the guides of the desired Bucky with the grooves on the C-Arm.



2 Push the Bucky forward until it locks securely in place.



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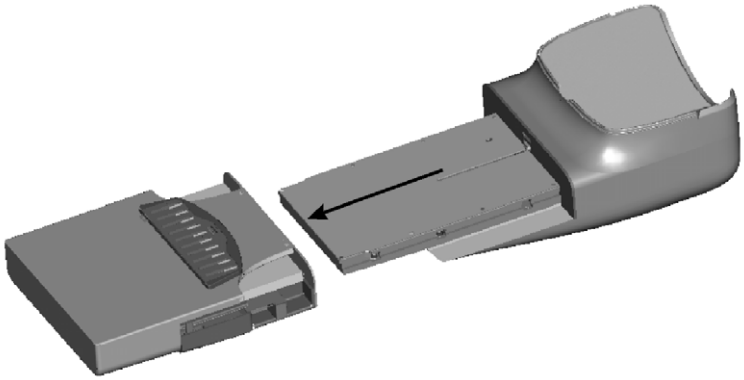
Removal of the Bucky

Pull the Bucky from both sides and pull it away from the C-Arm. Use both hands when removing the Bucky.



NOTE!

See more information of accessories in Special Exposures section.

Exposures with the Magnification tunnel

The magnification tunnel produces a magnified image of the breast. This is done by having a certain distance between the object and the film. Magnification factors 1.6x, 1.8x and 2.0x are possible with the MultiChoice magnification tunnel.

3.4.5 Insertion and removal of the face shield

The face shield is used to keep the patient's face or ear lobes out of the X-ray beam during exposure.

Insertion

Install or remove the face shield with a single horizontal movement along the grooves (left image below). Accidental pinching of the patient during the auto release of the compression paddle or some other situation is prevented as the face shield moves upwards from the face shield holder and away from the patient (right image below). If the face shield has come off in such, or some other situation, insert it diagonally back to the holder.

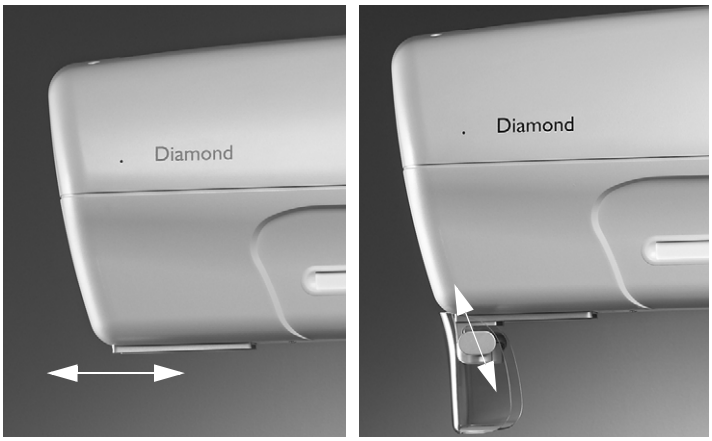


Fig 3.4. Insertion of the face shield

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Removal

Pull the face shield out horizontally out until the lock is released. Store the shield safely in order to avoid scratches and other physical damage.

3.4.6 Diaphragms

Diamond comes with built-in motorized diaphragms that are automatically adjusted to the required x-ray field size.

3.4.7 Additional product accessories

Diamond can be upgraded with the optional Delta 32, direct digital camera that can be used for spot, stereotactic, interventional or 3-dimensional TACT® imaging.

The ID II film identification camera exposes the all necessary patient and examination information onto the film when DIN standard (daylight) mammography film cassettes are used.

The Film marker kit (refer to Diamond Accessory Catalog (86503-IMG) for the order code for various languages) stores some information on the patient examination on to the film.

The Alpha Shield is available for additional protection of the user.

3.4.8 Connections to the system

Diamond has two RS232 serial ports that can be used to transfer information between Diamond and external devices.

Relay contacts are provided to enable the connection of room door entry warning lights. The system also has proprietary connections, e.g., for the Delta 32, stereotactic unit.

Diamond ports:

1 COM1

2 COM2 for film marking and label printing

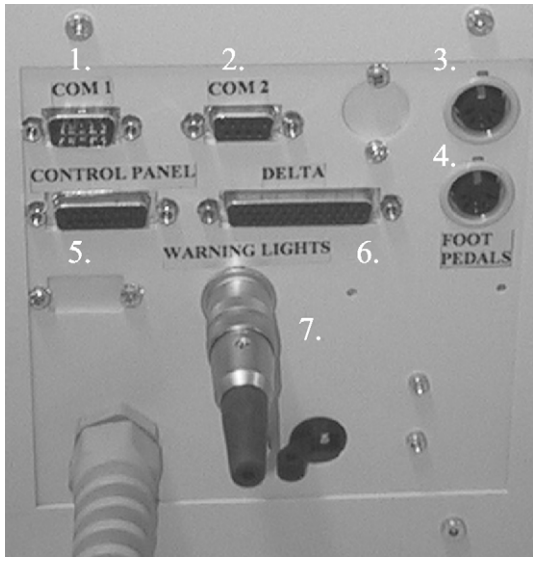
3 Foot pedal

4 Foot pedal

5 Control Panel

6 Delta 32

7 Warning lights



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4 User interface characteristics

4.1 AUTOPOINT DETECTOR

The **AutoPoint detector** is a highly sophisticated mammography **Automatic Exposure Control** (AEC) system. The image receptor base holds the AutoPoint Detector. This comprises 8 separate specially shaped Automatic Exposure Control (AEC) detectors. AutoPoint feature automatically selects the most appropriate detectors (primary and secondary) and calculates exposure time. This is especially useful in the following cases:

- consistent selection of the detector based on actual breast density, not on visual appearance
- more homogeneous optical densities all over breast image are generated
- when small breasts are examined

Three D-shaped detectors are positioned at the front edge, three oval detectors towards the back along centerline and two oval detectors either side of the centerline. The active area of a D-shaped or an oval detector is within a rectangular area of 4x1.5 cm and the oval detector within 4x3 cm.

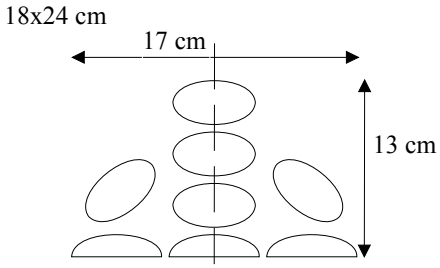

Fig 4.1. AutoPoint detectors

The measurement distance range of the AutoPoint detectors from front to back is 13 cm. The maximum width of the area covered by the detectors in the front is 17 cm. The detectors at the front edge are 5 mm from the edge of the film.

The AutoPoint Detector has two modes of operation, automatic and manual. In the automatic mode, the system selects the most appropriate detector to measure the radiation coming through the breast. Depending on set-up, a secondary detector with lower weight may also be selected. In manual mode the user selects the detector.

The selection between automatic (AutoPoint) and manual selection of the AEC detectors (button 9) is made at the Position Control Center. If AutoPoint mode is selected, the AutoPoint LED lights up at the Positioning Control Center and on the Control Panel. When the LEDs are off, the manual mode is selected. The user can select the required detector from the selection buttons (9). An LED turns on to indicate the selected detector.

NOTE!

If interpolative detector selection is used to lighten up less dense sections of the breast, it will also lighten up the most dense areas of the breast.

The Diamond system recognizes the compression paddle (and the cassette holder, depending on the PaddleLogic settings) in use and collimates the x-ray field size and disables those detectors that are outside of the radiation field or not under the compressed part of the breast.

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Detectors are not moved mechanically, but are selected by software.

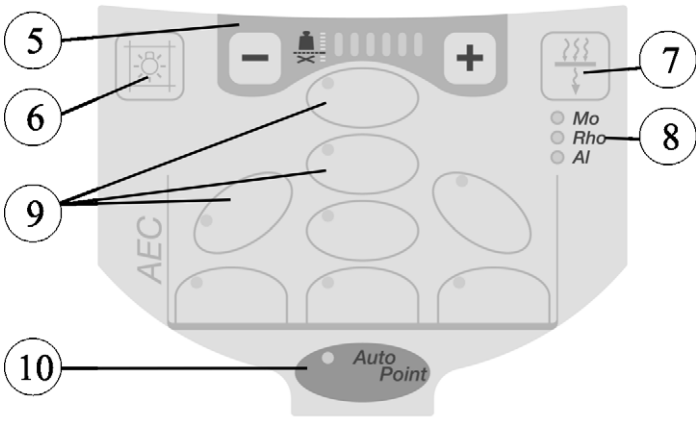


Fig 4.2. Positioning Control Center membrane panel

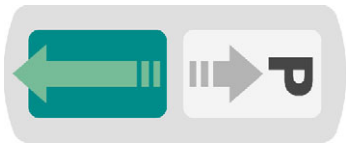
4.2 COMPRESSION FORCE DISPLAY & SELECTION

The selected force is shown on an LED display. The force values are programmed by your service technician and the maximum value can be from 78N (8kg / 18lbs) to 200N (20.4kg / 45lbs). User selection of the compression force limit is made using the compression force control buttons (5).

4.3 PARKBACK

The tube can be motor-driven backwards 19 cm (7 1/2") for totally free access to the breast from above. This is particularly useful in oblique and lateral positioning or for biopsy procedures. The motorized movement is controlled by buttons located on both sides of the tube head and also from buttons on top of the tube head.

Pressing the button drives the tube head until it comes to its end position. If it meets an object, it will stop. The ParkBack button may be pressed once or continuously, depending on the country-specific regulations for motorized movements. Pressing any button will stop all movements.



NOTE!

The moving tube head may alarm the patient. Please inform the patient that the tube is about to move and that it will stop automatically if it meets an obstruction.

The tube head can be programmed to move back automatically (if country-specific regulations allow this) if the C-arm drives to projections over 15°.

If the patient's head is in the way of the movement, the tube head either stops or drives back again. If the tube head is in the park position when the exposure button is pressed, it will automatically drive forwards into its exposure position first. This happens before X-ray tube 'Preparation' (preheat) phase takes place. If the exposure button is released, the forward movement stops. This automatic drive function is disabled with biopsy paddles and Delta 32 or if no cassette holder or paddle is attached.

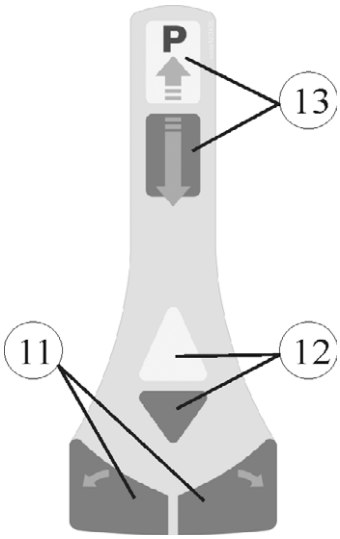


Fig 4.3. Control buttons at the top of Diamond

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If necessary, the automatic drive function can be disabled by your service technician.

The face shield may remain attached during movement of the tube head.

4.4 ProForm Synchro Buckies

All surfaces of Diamond that come into contact with the patient are smooth and rounded, with no seams or screws. The result is an increase in patient safety and comfort.

In order to achieve round corners and smooth surfaces in parts of the Bucky that come into contact with the patient, the cassette is loaded from either side from the rear end of the Bucky. This means that the front side of the Bucky has no openings until about 7 cm (with 18x24 cm film) back from the front edge on either side. When the cassette is inserted into either opening, it is automatically moved forward to the correct position at the front edge of the Bucky, ready for exposure. After an exposure the cassette is automatically moved back again to the opening ready for removal from either side. The cassette is also moved back automatically in some error conditions. The motorized cassette movement system allows manual cassette removal in the event of power failure or system malfunction.

All Buckies are daylight type (DIN) cassette. The ProForm Synchro Bucky consists of a one-part carbon fiber cover with rounded corners. Buckies utilize a common grid motor integrated into the Diamond's C-Arm for both Bucky sizes.

Fig 4.4. 18x24cm Bucky

4.5 PaddleLogic

Diamond PaddleLogic feature enables adjustment of the collimation and the available AutoPoint detectors separately for each paddle (see the image below for reference). For a small biopsy paddle the collimation (gray rectangle) can be adjusted to allow the exposure only to the region of interest: the coordinate system and the volume available for biopsy. Also, the AEC detectors allowed for AutoPoint can be limited. Especially with paddles of small size the detector(s) that is/are completely outside the metal frame can be blocked out.

Tell your service technician whether you want your Diamond to collimate according to the paddle or to cassette/paddle types. If the latter one is selected, then Diamond compares the collimated field sizes of the paddle and the cassette holder. The smaller one of these two is selected.

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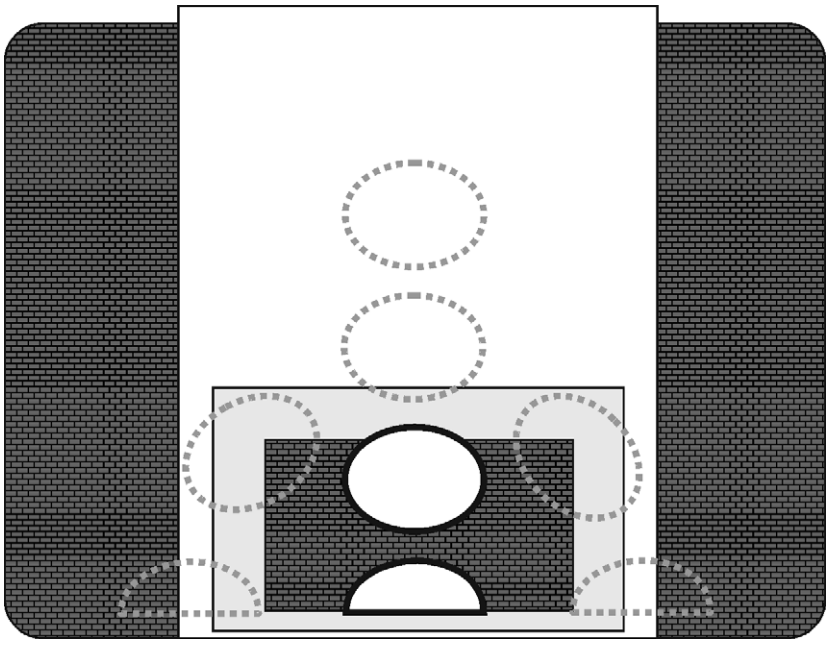

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5 Operating procedures

5.1 Anatomic C-Arm Rotation (ACR)

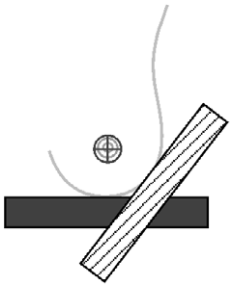

Fig 5.1. Anatomic C-Arm rotation (ACR)

Diamond has a motorized C-Arm that has a rotation range of (185°). The axis of rotation is close to the film plane so that the image receptor is able to follow the contour of the breast. This movement, Anatomic C-Arm Rotation (ACR) minimizes the need to adjust the height of the C-Arm when rotating between CC and OBL projections.

The C-Arm rotation angle is digitally displayed. C-Arm movements are inhibited under compression of more than 30 Newtons. The separate patient handles are located on the C-Arm.

Fig 5.2. C-Arm rotation display

NOTE!

In order to maximize patient safety, show the patient the location of the emergency button and explain its use. Check periodically that the emergency buttons work correctly. Press one of the emergency buttons and check that no such motorized movement is allowed that affects the patient (Tube head, ECS, Z-movement, C-Arm and Stereo). The movement can also be canceled by pressing any button on Diamond unit, except on the Control Panel. All motorized movements should stop. Release the emergency stop button, then repeat the test using the emergency button on the opposite side of the unit.

WARNING!

During the rotation of the C-Arm, keep clear of the moving parts of the unit so that no body parts could are struck by or become trapped in the unit, causing possible injury.

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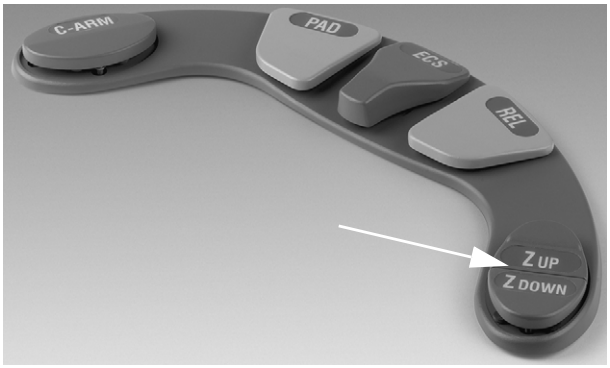
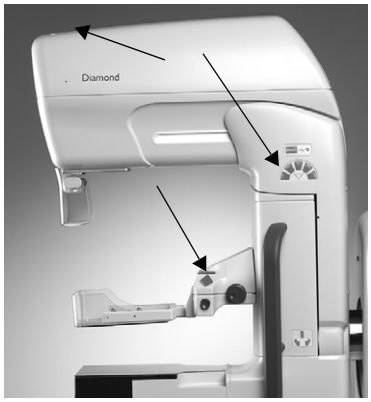
5.2 VERTICAL MOVEMENT (UP AND DOWN MOVEMENT)

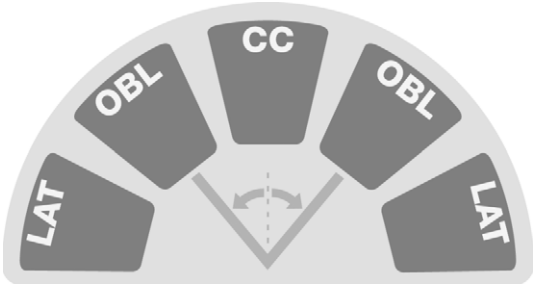
The control buttons for the vertical movement of Diamond's motorized C-Arm are located near the C-Arm rotation controls, at the Position Control Center, at the foot pedals and on top of the tube head.



5.3 SELECTION OF THE PROJECTION ANGLE

The C-Arm rotates ±185° from the vertical position (0°). Various control buttons are provided for convenience to drive the rotation movement. These are located together with the vertical movement control buttons at the Position Control Center and on top of the tube head there is a central membrane switch panel. The Diamond C-Arm also has buttons on both sides that conveniently drive the carriage CC, OBL and LAT-projections.





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C-Arm AutoDrive

The C-Arm AutoDrive feature drives the C-Arm to the selected projection angle after the button has been pressed once. This feature is disabled by software when no paddle or biopsy paddle is attached. In some countries or areas, this feature has to be disabled by the service technician. The C-Arm AutoDrive may be configured (paddle up function) to operate only when the compression arm is up in the home position (no compression). The paddle up function drives the compression arm to the home position after automatic compression release (Auto Rel).

Motorized rotation is possible even with maximum ECS (Easy Compression System) elevation, but during compression of more than 30 Newtons, rotation movements are inhibited. The rotation speed may be adjusted by your service technician. The rotation angle can be seen on the digital display located on the C-Arm. The C-Arm rotation buttons drive the C-Arm to any angle within the usable range.

Mirror angle feature

If the mirror angle feature is enabled, the C-Arm drives after an exposure to an equivalent angle on the opposite side (passing the CC position) of the C-Arm.

The OBL buttons drive the C-Arm to a predefined default angle that may afterwards be fine-tuned to the required angle. Pressing the other OBL button after the exposure (within 30-180 seconds, adjustable) causes the C-Arm to drive automatically to the same but opposite angle. The LAT-buttons drive the C-Arm to the lateral (90°) position. If the C-Arm angle has been adjusted with the fine-adjustment buttons, then pressing the opposite LAT-button after exposure causes the C-Arm to rotate to the same but opposite angle.

The projection buttons may be set by your service technician to drive automatically after the button has been pressed once, to drive automatically if compression paddle is completely up, or to press the button continuously (e.g., in biopsy procedure).

Example of the angle selection

NOTE!

When the C-Arm is being driven to CC, OBL or LAT angles, the movement may be stopped by pressing any button.

NOTE!

Pressing the emergency button always stops right away all such motorized movements, which affect the patient (Tube head, ECS, Z-movement, C-Arm and Stereo).

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Without fine tuning

1 Press the OBL button.
2 Compress the breast.
3 Make an exposure.
4 Press the opposite OBL button.
5 The C-Arm drives to the equivalent angle on the opposite side of the unit.

With fine tuning:

1 Press the OBL-button.
2 Make further adjustments to the projection angle using the C-Arm rotation buttons.
3 Compress the breast.
4 Make an exposure.
5 Press the opposite OBL button.
6 The C-arm drives to the equivalent angle on the opposite side of the unit.
7 Pressing the CC-button will return the C-Arm to the CC position (0°).

5.4 BEAM FILTER SELECTION

Diamond has three X-ray beam filters: Molybdenum Mo (0.025mm), Rhodium Rh (0.025mm) and Aluminum Al (0.50mm). If required, Diamond can be set to automatically select the most appropriate X-ray beam filter. All filters are motorized and the beam filters can be used automatically, if Auto Filter is switched on. Molybdenum and Rhodium are used in the kV range of 15 to 35 kV, whilst the Al-filter is used in the kV range of 36 to 39 kV.

Manual selection of the beam filter is the default setting, but the filter can also be selected automatically in Auto-kV and Auto-Time modes. The selected filter is indicated with a light next to the appropriate filter selection button. For large and dense breasts, the Rhodium filter should be used to reduce the exposure time and the patient dose.

NOTE!
After the exposure, the timer display shows the actual exposure time.

NOTE!
When using the Rhodium filter, do not increase the kV-setting.

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WARNING!

Use of Rhodium is recommended only on breasts that are thicker than 6 cm or very dense.

5.5 COLLIMATOR

5.5.1 Diaphragms

Diamond has an automatic motorized collimator that allows any rectangular collimation. For other collimated shapes, corresponding special diaphragms must be inserted manually. When you fit a cassette holder and compression paddle on to the unit, Diamond recognizes the cassette and paddle size and selects the correct collimator aperture. The type of cassette holder is displayed in Control Panel LCD display. If special diaphragms are necessary, these are inserted manually.

NOTE!

If the collimator plates do not return to the home position, exposures are prevented by Diamond software and an error message is displayed.

5.5.2 X-ray field illumination light

The X-ray field illumination light is switched on automatically when the compression pedal is pressed down, the tube head is being driven forward or the collimator light switch is pressed (inactive when the tube head is in the back, in the park position). The light is switched off automatically after 40 seconds (factory default, the service technician can adjust the time within 20 - 60 seconds) or the light turns off when the exposure button is pressed to start an exposure or when the collimator light switch is pressed. The light helps to check that the collimation and patient positioning are correct.

When the Delta 32 is attached, the collimator light stays on for 80 seconds (factory default, the service technician can adjust the time within 20 - 90 seconds) to help provide good illumination over the breast. The light can also be used when the tube is in the park position (driven backwards).

WARNING!

As the light bulb gets very hot whilst turned on, do not touch it during and immediately after use.

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5.6 COMPRESSION SYSTEM

Good mammographic image quality requires sufficient compression of the breast. The breast is compressed against the cassette holder with the compression paddle, which is either manually moved using the manual compression wheel or motor-driven using the foot pedals.

5.6.1 Paddles

A compression paddle consists of an acrylic compression plate and a metal supporting frame with fixings used to attach the paddle to Diamond's compression paddle arm. Graphics indicating the AutoPoint AEC detector locations are silk screen printed onto the acrylic part of each paddle to the extent the size of the paddle acrylic allows. Paddles are attached with a straight horizontal movement and removed by first pressing either one of the compression paddle release keys (7) and then pulling the paddle out with a horizontal movement.

Fig 5.3. Compression paddle release key

The surfaces between the compression paddle/arm and the cassette holder are smooth to enable safe, comfortable positioning by the radiographer/technologist.

5.6.2 Compression Foot Pedals

A compression foot pedal has the following foot switches:

Fig 5.4. Compression foot pedal

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1 C-Arm

When the C-Arm foot switch is pressed, only the C-Arm is driven towards the tube head at a slow speed.

2 PADDLE

When the Paddle foot switch is pressed, only the compression paddle is driven towards the image receptor. The collimator light is turned on automatically at the same time. Before the paddle touches the breast the speed of the paddle is high. Once the breast is compressed the speed slows down. Both the drive speed and the threshold where the speed change occurs on contact with the breast are adjustable by your service technician.

3 ECS

When the ECS foot switch is pressed, the C-Arm is driven towards the tube head and the compression paddle is driven towards the image receptor, so that the paddle appears to be stationary in relation to the patient. This means that the cassette holder (Bucky or magnification tunnel) is used to apply the compression to the breast against the 'stationary' paddle.

4 REL

When the REL foot switch is pressed, the C-Arm is driven towards the image receptor to its rest position and the compression paddle is driven towards the tube head, removing compression to the breast. As long as the C-Arm is not yet in its rest position, the paddle is driven at the same speed as the C-Arm, thus the paddle appears to be stationary. Once the C-Arm movement stops, the compression paddle is driven towards the tube head until it reaches the upper microswitch.

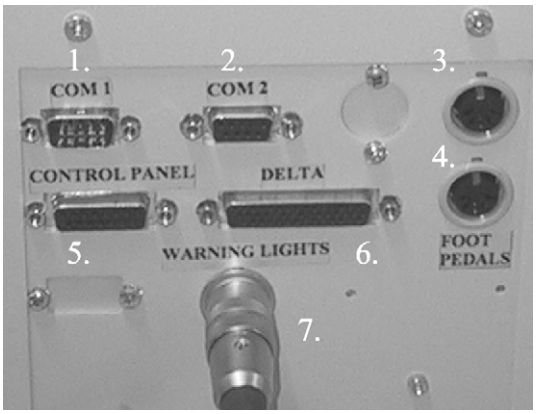
5 Z-UP

When the Z-UP foot switch is pressed, the carriage is driven towards the tube head.

6 Z-DOWN

When the Z-DOWN foot switch is pressed, the carriage is driven towards the image receptor.

There are two compression foot pedals supplied with the Diamond. These are connected with cables to the back of the column (3 and 4 in the image).



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WARNING!

Ensure that the pedals are placed so that the patient cannot reach the switches during positioning or imaging.

NOTE!

In the event that the patient faints, release the compression with the REL-pedal, or the emergency button, or the manual compression wheels, or switch the device off from the mains switch.

In order to ensure the correct and prolonged operation of the compression foot pedals, avoid rough handling of the compression pedal cables. For additional safety, Diamond's software control system checks that all command signals are passive during its start-up sequence.

5.6.3 Compression controls

With the Diamond, a manual or motorized compression can be used. The majority of compressions/positioning are performed motorized. The manual compression system is then used for the fine tuning of the compression, if necessary.

The PADDLE pedal drives the compression paddle downwards, the C-Arm pedal drives the C-Arm (note: not the carriage) in the direction from the image receptor to the tube head. The ECS pedal starts the ECS-compression where the image receptor compresses the breast against the fixed compression paddle. The REL pedal releases the compression.

The compression force pre-selection keys determine the maximum force that can be applied to the breast. The left key decreases and the right key increases maximum compression force limit.

Fig 5.5. Compression force pre-selection

The compression force limit is programmable by the service technician from 70N (16lbs) to a maximum of 200N (45lbs). For safety reasons, motorized compression may be limited in position 6, for example, to 200N (45lbs), dependent upon local regulations. As the manual compression wheel allows considerable compression force to be applied - up to 300 N (66 lbs.), care must be taken not to injure the breast.

Remember, care must be taken in order not to injure the breast. The compressed breast thickness and the compression force are displayed in the C-Arm display, see Figure 5.7, Positioning data display. The compression system also incorporates a mechanical force limit, which is adjusted to 300 N (67 lbs.) at the factory. The service technician may re-adjust this limit.

Manual compression release is also possible without power to the unit using the manual compression wheels.

5.6.4 Motorized compression

Compression is controlled in two ways: either using foot pedals or manual compression wheels. In the event of power failure, the compression releases automatically, except when the Delta 32 biopsy unit is connected to the system.

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5.6.5 Manual compression wheels

The manual compression wheels allow manual decrease or increase of compression force. The wheels (8) are located on both sides of the compression arm Position Control Center.

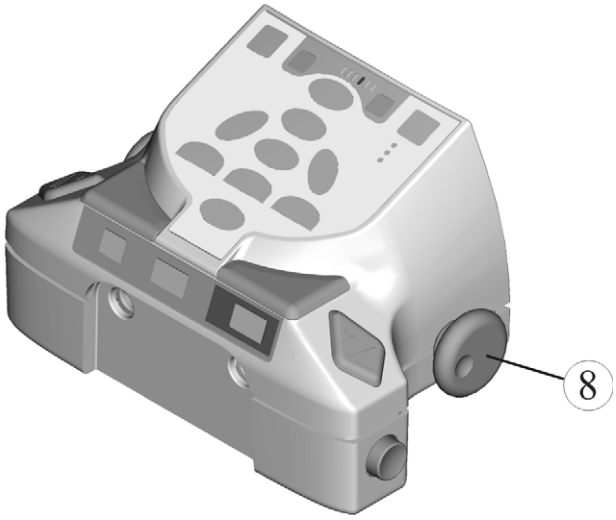

Fig 5.6. Manual compression wheels

5.6.6 ECS compression system

ECS (Easy Compression System) adds one more unique movement to GE Healthcare mammography systems: the independent movement of the C-Arm in relation to the compression paddle. This movement is also independent of the angle of the C-Arm and it is different from the normal up and down movement of the C-Arm carriage. With the ECS movement, the breast is compressed from the mobile margin (i.e., from below). The movements are controlled using the ECS foot pedal. After an exposure the auto-release will release the compression.

The ECS system uses the natural mobility of the breast to increase the clinical image quality and patient comfort. ECS makes it easier to elevate the breast and open the infra-mammary fold, thereby maximizing the amount of breast tissue visible in the image. In positioning, ECS does not replace the skill of an experienced radiographer/technologist but helps her carry out the positioning more easily.

In clinical usage the amount of images that have pectoral muscle visible in CC-projections has increased from 20% (the amount prior to the use of the ECS system) to 50%. The ECS compression system can also be used to perform conventional compression techniques.

ECS is also excellent in biopsy procedures. If the lesion is close to the chest wall, applying compression from below ensures that the lesion stays under the compression paddle. With standard compression the lesion may move away from the paddle.

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5.6.7 Positioning data display

The positioning data display shows the parameters that the system is able to measure during patient positioning (the ± symbols are not displayed):

1 Breast thickness, range 0 - 20cm, resolution: 0 to 9.5cm: 0.5cm; 10 to 20cm: 1cm

2 Compression force, range 0 - 350 Newtons, resolution 5 N

3 C-Arm angle, ±185° degrees, resolution 1°

1. **2.** **3.**

Fig 5.7. Positioning data display

5.7 PATIENT POSITIONING

NOTE!

Always advise the patient not to use deodorant prior to a mammographic examination! Certain deodorants can mimic micro-calcifications on the film.

NOTE!

In case the patient moves in the middle of a procedure or compression thickness is changed, in order to guarantee the accuracy of the examination the procedure should be started from the beginning.

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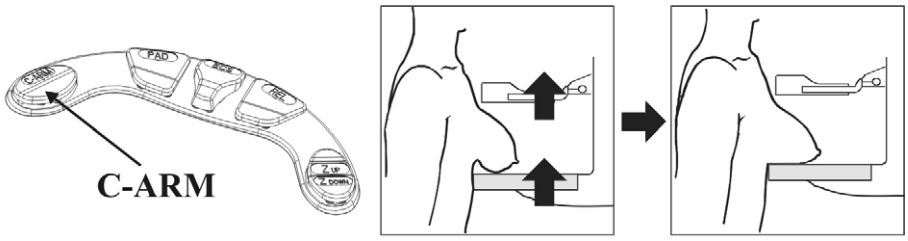
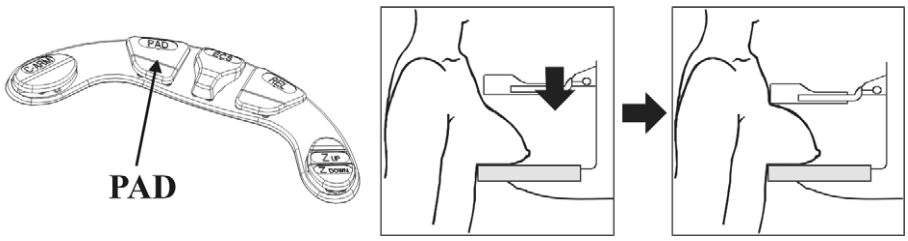
5.7.1 ECS movement

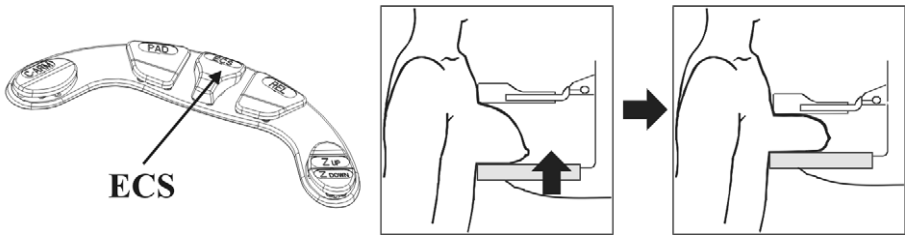
1 The C-Arm is driven upwards without applying compression, to open the infra-mammary fold.



2 The breast is compressed slightly with the paddle to hold it in place.



3 Final compression is applied by the Bucky or cassette tunnel from below using the ECS compression movement.



5.7.2 Cranio-Caudal (CC) Projection

1 Select the required film size, load the film into the cassette, and place the cassette into the cassette holder.

2 Make sure that the C-Arm is in the upright position (0º) by pressing the CC-key. Adjust the image receptor height using the vertical height control so that patient's nipple is in profile, no skin folds are present under the breast and that the infra-mammary fold is open. Refer to Fig. 5.8, Correct vertical position and Fig. 5.9, Incorrect vertical position.

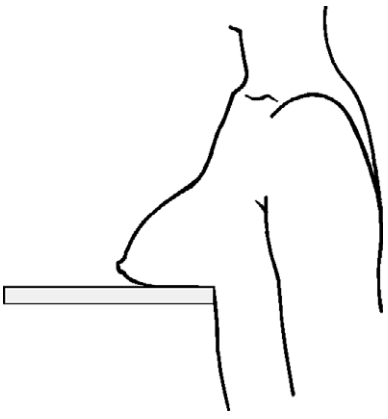


Fig 5.8. Correct vertical position

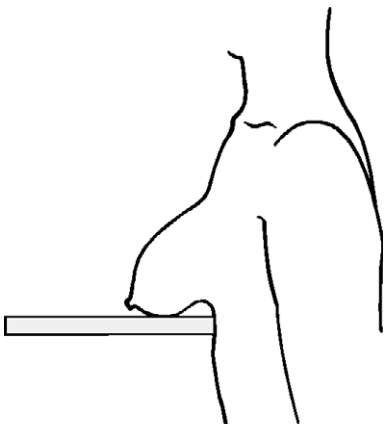


Fig 5.9. Incorrect vertical position

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3 Slightly rotate the patient medially and lean her towards the unit. Refer to Fig. 5.10, Patient positioning at cranio-caudal projection. Allow the patient to grip the hand grips, and lean towards the unit so that the cassette holder under the breast makes contact against the ribs.

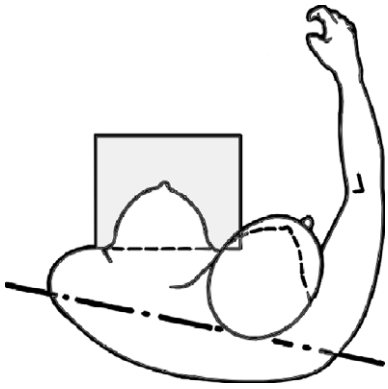

Fig 5.10. Patient positioning at cranio-caudal projection

4 Place the breast on the cassette holder so that it is symmetrical and totally covers at least one of the automatic exposure control detectors, as demonstrated by the graphics printed on the clear acrylic of the compression paddle. Manually select the most appropriate detector or use the AutoPoint automatic detector selection feature.

NOTE!

If the breast does not cover at least one detector or the breast has an implant, a manually selected exposure technique must be used.

5 Apply the compression to the breast using the compression foot pedal or the manual compression controls. Make sure that the nipple is not inverted. Smooth out any skin wrinkles that may have been caused during compression.

6 Position a film marker on the image receptor to the side of the lateral aspect of the breast. Turn the patient's head away from the X-ray beam.

7 Take note of the compression thickness display to achieve the correct compression for both breasts. When compressed correctly, the breast should be firm when palpated. The skin may become blushed, red or pink. Make sure that the ready light is on. Select or de-select the Auto Rel (automatic compression release) function.

8 Make the exposure by pressing the exposure button, and keep it pressed until the radiation indicator light goes out and the audible exposure indicator stops. Release breast compression (if not automatic).

9 Change the cassette and make an exposure of the other breast or move on to another projection.

NOTE!

In manual usage, the selected kV should produce an exposure time from 0.5 to 1.2 seconds. If exposures are longer than 1.2 seconds, increase the kV value. If they are shorter than 0.5sec., reduce the kV value.

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Fig 5.11. Cranio-caudal projection

5.7.3 Oblique projection

1 Select the required film size. Load the film into the cassette. Place the cassette in the cassette holder.

2 Rotate the C-Arm to the required oblique projection angle (35-60°) using the OBL-key. If automatic ParkBack is disabled, drive the tube head to the back to get more work space and better access to the patient.

3 Adjust the image receptor height using the vertical drive controls. Place the upper edge of the image receptor so that the axillary tail of the breast will be visualized.

4 Ask the patient to hold the arm on the side to be imaged, at a 90° angle and turn the patient slightly inwards to an oblique position. Rotate the patient towards the image receptor and place their breast onto the cassette holder so that it totally covers at least one of the AutoPoint AEC detectors.

5 Select the most appropriate detector or use the AutoPoint automatic detector selection function. Make sure that the lateral breast tissue is pulled forward.

6 Apply compression with the foot pedal or by using the manual controls. Make sure that the patient's nipple is in profile and that no skin folds are present. If the tube head is back, drive it forward. Check that the Ready light is on.

7 Make the exposure by pressing the exposure button and keep it pressed until the radiation indicator light turns off and the audible exposure indicator stops.

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Fig 5.12. Oblique projection

5.7.4 Medio-Lateral Projection

1 Select the required film size, load the film into the cassette and place the cassette into the cassette holder.

2 Rotate the C-Arm to the lateral position (90º) by pressing pre-programmed LAT-keys. If automatic ParkBack is disabled, drive the tube head to the back to get more work space and better access to the patient.

3 Adjust the cassette holder to a suitable height with the vertical drive controls. The cassette holder should reach the height of the patient's axilla. The medial portion of the breast needs to be in contact with the image receptor. Ask the patient to hold the hand grip and to lean towards the unit.

4 Place the breast on the cassette holder so that the breast totally covers at least one of the AutoPoint AEC detectors. This can be achieved by gently pulling the breast away from the chest wall.

5 Check that the breast covers the detector. Manually select the most appropriate AEC detector or use the AutoPoint feature.

6 Apply compression using the foot pedal or the manual controls. Make sure that the patient's nipple is in profile and no skin folds are present. If the tube head is back, drive it forward.

7 Check that the Ready light is on. Make the exposure by pressing the exposure button and keep it pressed until the radiation indicator light turns off and the audible exposure indicator stops.

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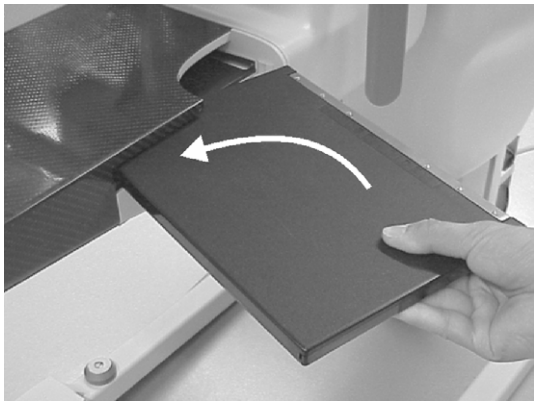
Fig 5.13. Medio-lateral projection

5.8 EXPOSURE PROCEDURE

5.8.1 Installing a cassette

1 Load the film into the cassette.

2 Open the lock to insert the cassette into the cassette holder by inserting the lower left corner of the cassette to the Bucky. Push then the cassette towards the front of the Bucky so that the upper left corner slides in.



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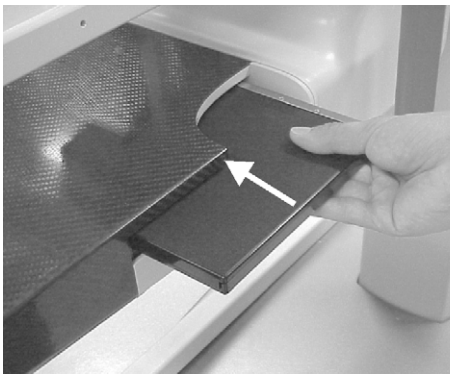
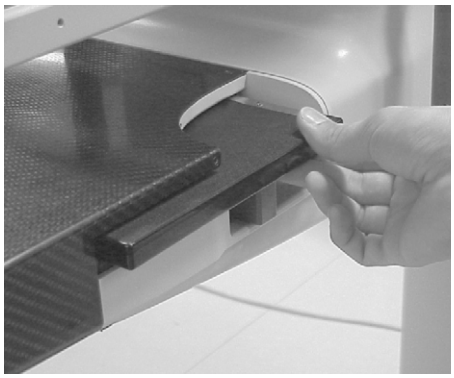
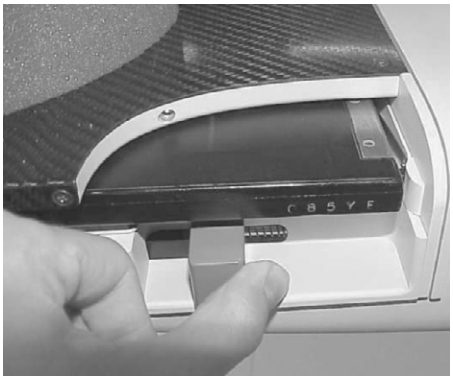
3 Slide (do not throw) the cassette in until the lock key returns to its normal position. Take care not to trap your fingers in between the cassette holder and the cassette.





Diamond has an automatic cassette loading mechanism that moves the cassette to correct position at the front edge of the cassette holder, ready for exposure. In case the cassette is inside, but in the back of the Bucky, pulling the cassette latch towards the front of the Bucky takes the cassette to the front for an exposure.



NOTE!

Diamond is configured to use daylight cassettes as standard.

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5.8.2 Diamond technique guide

Mo, Rh, Al

Film: Kodak Min R 2000, Screen: Kodak Min R 2000 and Min R 2190 Film: Fuji AD-M, Screen: Fuji AD Mammo Fine Film: Agfa HDR and HDR-C, Screen: Agfa HD and HD-S			
Compressed breast thickness	**Technique**		
	kVp	**Filter**	**Density**
< 3 cm	23	Mo	0
4 - 5 cm	24 - 26	Mo	0
6 - 7 cm	27 - 29	Mo or Rh*	0
> 8 cm	30 - 32	Mo or Rh*	0
Manual Techniques		**mAs**	**kVp**
Small breasts		16 - 40	23 - 25
Implants		80 - 175	26 - 29
Specimens (non-mag and mag)		4 - 16	20 - 23

Table 5.1 Diamond technique guide

NOTE!

Implant displaced views and specimens may be phototimed if sufficient breast tissue covers the photocell closest to the chest wall.

Comments:

1 Maintain exposure times between 0.5 and 2.5 seconds. Decrease kVp if times are less than 0.5 seconds and increase if they are more than 2.5 seconds.

2 If exposure times are within indicated times, use + or - density settings to achieve optimal film density.

3 Your technique may vary from those indicated above depending on film density preferences, processor or film irregularity, or different film/screen combinations.

4 ***Rhodium** - use for very dense breasts, 6 cm or greater. No need to increase kV.

5 Magnification views - increase technique by 2 - 3 kVp, if exposure time exceeds 5 seconds.

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5.8.3 Making the exposure

The Ready Light indicates that the unit is ready for exposure. The collimation, cassette holder and cassette must be in place.

NOTE!

If using a manual filter selection, check that the correct filter is selected.

1 Refer to Diamond tube loading chart for kV and mA combinations, if necessary.

2 Make the exposure by pressing the exposure button, and keep it pressed until the X-ray exposure terminates.

The X-ray exposure is indicated by the radiation light, the audible exposure indicator, and the accumulating exposure time on the control panel exposure time display. If the exposure button is released during the exposure, the exposure is terminated immediately and an error message is displayed on the LCD screen of the control panel.

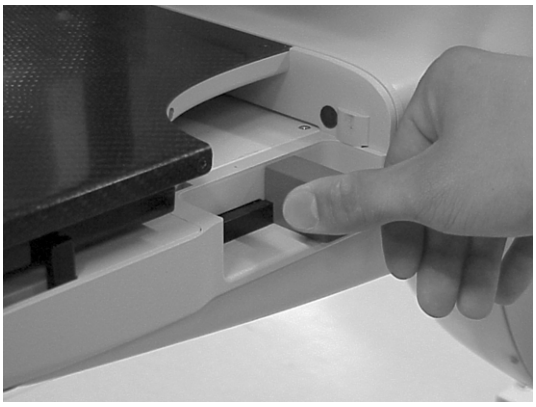
5.8.4 Automatic compression release

By default, Diamond releases compression automatically after exposure. The automatic release can be disabled from the control panel. When performing a manual biopsy procedure, compression may be released with the foot pedals or manual compression wheels. Automatic compression release (Auto Rel) will automatically switch off when a biopsy paddle is fitted.

5.8.5 Removing the cassette

Diamond's automatic cassette loading mechanism returns the cassette immediately after exposure, ready for removal.

1 If the cassette has not been exposed yet, it is still in the front end of the Bucky. In order to remove it, slide the cassette latch towards the back of the Bucky. This procedure returns the cassette to the rear end of the Bucky. In the event of a power failure or system malfunction, pull the cassette to the rear end with your fingers.



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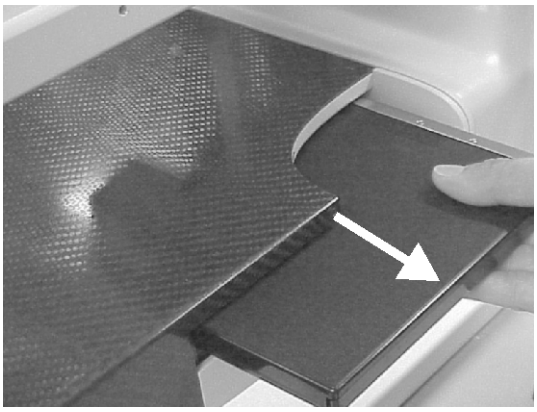
2 Remove the cassette by pushing the cassette lock release key towards the front end of the Bucky. Hold the key in the forward position with your middle finger and pull the cassette out with your thumb and index finger.

3 Pull the cassette out of the cassette holder.



5.8.6 Cooling period

After each exposure, there is a typical cooling period of 10 to 50s depending on tube loading, but it can also be longer. During this time an exposure cannot be made. If the exposure button is pressed before the cooling time has elapsed, the timer display will indicate the remaining cooling time.

If the Ready Light does not turn on 50 seconds after an exposure, refer to the **Troubleshooting** section.

5.9 FILM LABELING

There are three ways to identify films:

1 Using film markers that show the projection and year on the film.

2 Using a film identification camera that exposes all relevant information directly onto the film.

3 Using printed adhesive paper labels that are attached to the film.

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5.9.1 Film markers

The film markers provided for use with Diamond are positioned close to the film to prevent scatter. Markers can be moved sufficiently far to extend past the cassette's daylight ID marking window and into the imaging area of the film.

Each cassette holder has a plate onto which the film marker set is fitted. The corners of the marker set have round edges to ensure patient comfort.

5.9.2 Film Identification Camera

The digital ID camera exposes information directly onto the undeveloped film. The camera is connected to Diamond's serial port using a serial communications cable. Diamond's serial port is located at the lower rear cover of the unit. The camera can only be used with daylight cassettes.

5.9.3 Printed labels

Diamond can output information to a printer. In this way, printed film identification labels can be produced. One of two printer label sizes can be selected by your service technician:

- 36.7 x 101 mm
- 26.0 x 101 mm

For each of the four rows printed, the last 15 characters of the 40 on each row are freely programmable. The following is an example of the text produced by Diamond and printed on to a label:

```
1234567890123456789012345678901234567890
B Rh 0.02s 28kV 002mAs +0 HOSPITALxNAMEx
6.5cm 200N 180^/R 0.06mGy CODExxxxxxxxxx
15 / 09 / 04      R1/C1 12345 RADIOLOGIST
_____________________________ DEPARTMENTxxxx
```

	Explanation
B	**B**ucky / **C**assette tunnel / **M**agnification
Rh	Rhodium / Molybdenum / Aluminum filter
+0	Density correction
28kV	kV
002mAs	mAs
0.02s	Exposure time
6.5cm	Breast thickness
200N	Compression force
180^/R	C-Arm tilt angle, ^= degrees (°), to the /Right or /Left
0.06mGy	Average patient dose

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	Explanation
15 /09/04	Date of examination (day/month/year)
R1/C1	Site of the primary/secondary detector (L1, L2, C1, C2, C3, C4, R1, R2)
12345	Exposure counter, up until 99999
_____	The patient's name must be handwritten after printing the label

5.9.4 Printer connection

A label printer may be connected to Diamond's serial port using a serial communication cable. Diamond's serial port is located at the lower left of the unit's rear cover. Use digital ID Camera to print the information permanently onto film.

Diamond ports:

1 COM1

2 COM2 for film marking and label printing

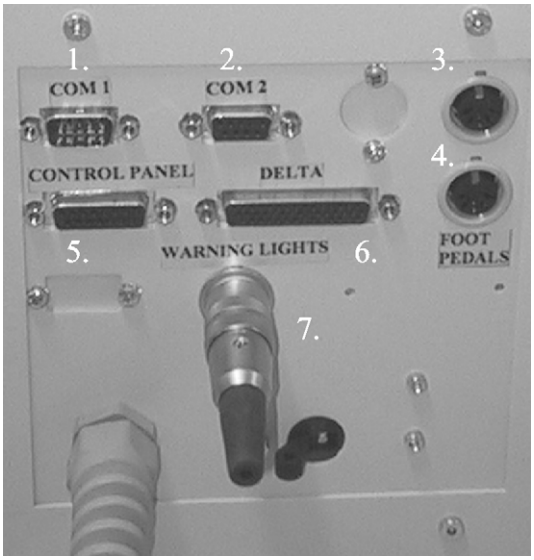
3 Foot pedal

4 Foot pedal

5 Control Panel

6 Delta 32

7 Warning lights



The Film ID Camera and a label printer use the same serial port, i.e., only either one of the devices may be connected at one time.

CAUTION!

When connecting Diamond to a printer or a similar combination, make sure that connection conforms to IEC60601-1-1. The leakage current values must not exceed the limits. Use isolation transformer if necessary.

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5.10 SPECIAL EXPOSURES

5.10.1 Magnification studies

By placing the breast at a distance from the film causes the image to be magnified. This increases the size of the smallest objects (micro-calcifications) above the grain size of the film-screen combination thus improving the image quality.

WARNING!

As source to skin distance is decreased when using a magnification tunnel, avoid unnecessary magnification examinations or keep the focal spot to the skin distances as large as possible in order to keep the skin dose as low as possible. Do not perform screening with a magnification tunnel!

The air gap between the breast table and the cassette reduces scattered radiation and further improves image contrast. A small focal spot is essential for good magnification image quality and therefore a true 0.1mm focus is needed. The Diamond X-ray tube features a Gaussian 0.1mm focal spot and during magnification studies this is automatically selected.

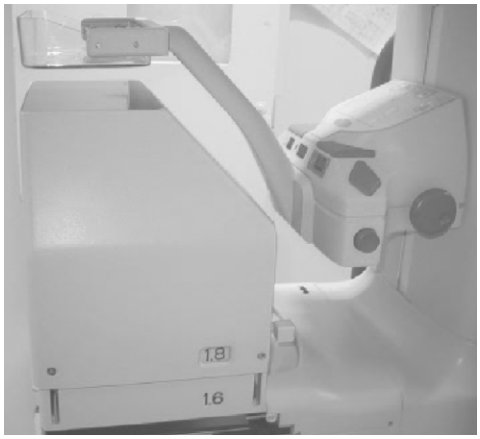
Although the object may be visualized well, this is offset by the fact that only a small area of the breast can be imaged at a time.

For magnification studies the Diamond uses the MultiChoice magnification tunnel. One tunnel is used for all magnification factors 1.6x, 1.8x and 2.0x. The factor is a user preference and can be changed by the user. The film format in magnification studies is always 18x24cm.

Magnification studies can be performed by applying compression to the whole area of the breast, which is all imaged or by applying compression only to a specific area, called spot compression. In whole field imaging, a larger area can be studied on one image, for example, when it is not known where the area of interest lies in the breast.

5.10.2 Magnification procedure

Remove the face shield and install the magnification tunnel. The magnification tunnel is inserted and removed the same way as the cassette holders. During insertion of the magnification tunnel, make sure that you hear two clicks, one on each side. This means that the tunnel is locked and stable. If the tunnel is not locked correct, it will slide down during compression .



Follow the general patient positioning procedure. The size of the top of the magnification tunnel corresponds to the area which can be magnified onto the 18 x 24cm film size.

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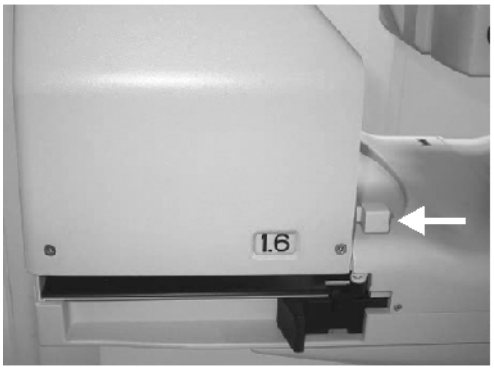
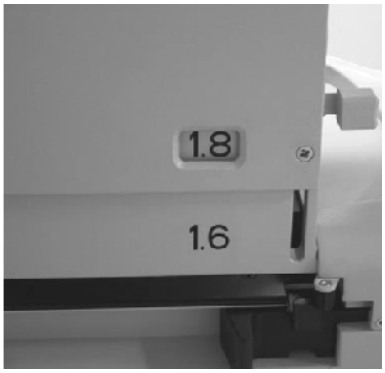
5.10.3 Adjustment of the magnification factor

The window in the magnification tunnel design displays the current magnification factor. It can be changed by pushing in the small lever in the back of the tunnel frame and then lifting up or lowering the tunnel.



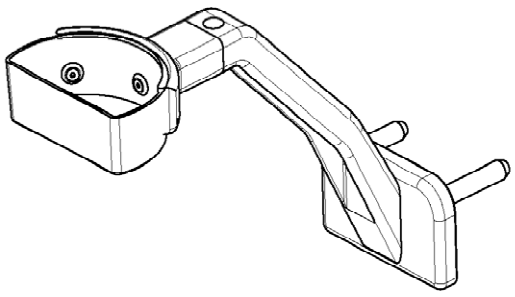


If you are using the spot magnification compression technique, ensure that the area of interest is under compression and in the light field.

The small focus (0.1mm) is automatically selected for magnification exposures. In magnification manual mode kV values starting from 20 kV can be used.

5.10.4 Spot Magnification

Spot compression also compresses the breast more, thereby allowing the use of a lower kV-setting, which results in improved image quality. However, positioning using spot compression is more difficult to achieve.



X-ray beam should be collimated to the compressed area. This reduces scattered radiation to the image area, so improving contrast and also reduces the patient dose. However, the final image may be harder to read on the viewing box due to the density difference between the exposed area of the film (the image) and the unexposed areas of the film. The use of a mask for reading instead of exposing full image is advisable.

Spot compression applies local compression to a particular area. There is less overlapping of tissue structures, which improves visualization.

NOTE!

Be careful when using spot compression as the compression effect is greater on a smaller breast examination area.

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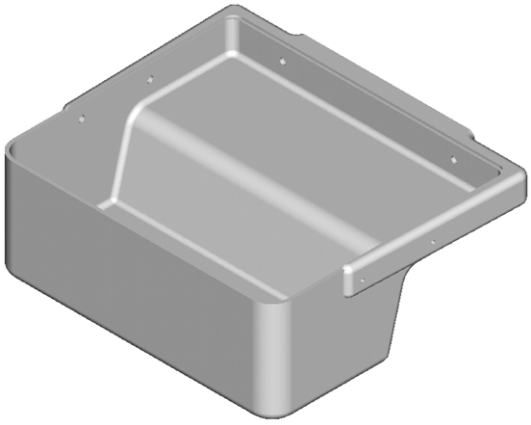
5.10.5 Implant exposure

The implant paddle allows very good access to the breast during positioning. The paddle can be best utilized with small breasts, with breasts that have a silicon implant or with male breasts. It also provides excellent compression in oblique or lateral projections because it extends to the whole width of the 18x24 cm film format.



In populations where a greater proportion of women have small breasts, the implant paddle may be used as the standard paddle, together with the 21x24 cm paddle.

NOTE!

If the breast does not cover at least one AEC detector or implant is known to cover the AEC detectors, a manually selected exposure technique must be used.

5.10.6 Manual biopsy

WARNING!

Diamond motorized vertical or rotation movements are enabled when displayed compression force is below 30N. Verify before starting biopsy that you have adequate compression force.

There are different types of biopsy paddles available for use with Diamond, each with different openings. These openings are available as holes with a diameter of 18mm, holes with a diameter of 9mm and as rectangular opening of 50x90mm. User preference determines which type of paddle that is used. Biopsy paddles are used in manual biopsy procedures for Fine Needle Aspiration (FNA) or lesion marking.

1 Attach the biopsy compression paddle in the normal way. Diamond recognizes the paddle in use and chooses the correct collimator format automatically. Diamond turns the auto compression release off whilst the biopsy paddle is attached. Automatic drive to projection angle is also disabled.

2 Clean the biopsy compression paddle and breast area carefully.

The biopsy procedure can be performed at all projection angles, but an angle should be used that provides the shortest possible distance for the needle from the skin to the lesion.

3 Rotate the C-Arm to the appropriate angle.

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A biopsy chair should be used for the patient that provides good support to the patient's back and arms. An optional biopsy chair is available from GE for use with Diamond.

WARNING!

Ensure that the pedals placed so that the patient cannot reach the switches during positioning or imaging.

NOTE!

Make sure that C-Arm can rotate freely and that it is not obstructed in such a way that it may strike an object causing the system to tilt. Also ensure that the users does not position themselves between the C-Arm and any obstruction, as injury could result. If necessary, use emergency stop buttons or any button on the Diamond unit, except if it is on the Control Panel.

Manual biopsy procedure

1 Make the patient comfortable in the sitting position.

2 Adjust the compression paddle to a suitable height using the foot pedal or manual controls or with the vertical movement keys.

3 Place the breast on the cassette holder so that the breast totally covers at least one AEC detector.

4 Turn the patient's head to the side. Apply compression using the foot pedal or manual controls.

Take care that the patient's nipple is in profile and no skin folds are present. Do not compress the breast quite as much as in a routine examination, since it must remain compressed for some time until the X-ray film is developed. However, the compression must be enough to prevent the breast from moving. Too little compression allows the breast to move and the biopsy will be inaccurate.

NOTE!

Make sure that the patient's head is out of the light field.

5 Make the exposure by pressing the exposure button and keep it pressed until the radiation indicator light turns off and the audible exposure indicator stops. Do not release the compression.

6 Develop the film. The holes in the compression paddle can be seen on the image, and localization of the biopsy target can be made.

NOTE!

In case the patient moves in the middle of a procedure or compression thickness is changed, in order to guarantee the accuracy of the biopsy, new image should be taken or the procedure should be started from the beginning.

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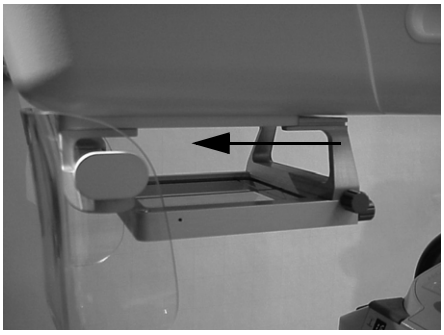
7 Carry out the biopsy procedure and when completed, release the breast compression.

8 Attach a cross hair diaphragm as described below. When cross hair diaphragm is used, the face shield should remain attached during the procedures.



5.10.7 Stereotactic option

Diamond's optional stereotactic feature of the Diamond can be used together with the ECS compression system in order to perform high-quality biopsies. Three-dimensional digital images can be acquired with Delta 32 TACT®-option.

5.10.8 FNA procedure

In the FNA procedure, a sample of the breast tissue is taken for cytological analysis of the lesion. In lesion marking the lesion is marked for surgical biopsy either with a steel wire or with dye. The surgeon then follows either the wire or color trail to remove the correct lesion.

In a procedure the breast is imaged with a biopsy paddle from one projection.

The openings from the paddle can be seen in the image and with their help the location of the lesion in this plane can be estimated.

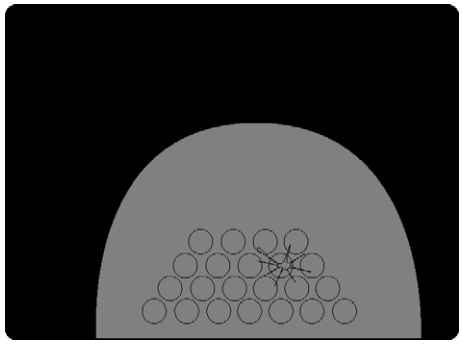


Fig 5.14. FNA paddle

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How deep in the breast the lesion is can be estimated from images that have been taken using a second projection. These can be taken earlier or during the same procedure.

NOTE!

The collimator light turns on when tapping the foot switch and turns off after 40 seconds. Do not tap the foot pedal repeatedly as this can alter the amount of breast compression, resulting in impairment of biopsy accuracy. For positioning, switch the collimator light on with the collimator light switch.

The biopsy needle is inserted into the breast after careful estimation and another image is taken to ensure that the correct localization has been achieved.

NOTE!

Check the C-Arm rotation angle before performing a biopsy procedure.

5.10.9 Lesion marking

NOTE!

Release compression manually so that the hub of the needle does not to catch on the localization paddle.

1 Mark the lesion with a steel wire or with dye for surgical biopsy. If you use a control wire, fix it to the breast with tape.

2 Check the location of the wire end with an exposure. If required, the location of the wire is altered and checked with another exposure.

Correct steel wire localization can be determined after insertion by producing another image at a second projection angle. If this is done, the amount of compression applied has to be quite small to ensure that the localization wire does not move.

In a marking procedure, the breast is imaged with a biopsy paddle from one projection. The openings from the paddle can be seen on the image and with their help, the location of the lesion in this plane can be estimated.

5.10.10 Spot exposure

The spot compression paddle is used in clinical studies with the 18x24cm Bucky or cassette tunnel. It applies local compression to a specific area of the breast. This moves the different tissue structures from overlying each other giving improved visualization of those structures. The breast tissue at the compressed area is also thinner allowing the use of a lower kV setting, which improves image contrast.

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X-ray beam should be collimated to the compressed area. This reduces scattered radiation to the image area, so improving contrast and also reduces the patient dose. However, the final image may be harder to read on the viewing box due to the density difference between the exposed area of the film (the image) and the unexposed areas of the film. The use of a mask for reading instead of exposing full image is advisable.

Insert the cassette and compression paddle. Diamond will recognize the paddle and use the correct collimation. Rotate the C-Arm to the required angle for the projection to be performed. Adjust the cassette holder to a suitable height with the vertical adjustment button.

Select the most appropriate AEC detector for the examination ensuring that it is totally covered by the breast when under the compression paddle. After selecting the paddle, the AEC system operates only within the defined area. Diamond prevents the selection of an AEC detector that is not within the area of (not under) the compression paddle in use.

Apply compression using the foot pedal or manual controls. Smooth out any skin wrinkles that may have occurred during compression. Ensure the patient's head is out of the collimator light field.

Make the exposure by pressing the exposure button, and keep it pressed until the radiation display indicator light turns off and the audible exposure indicator stops.

WARNING!

Care must be taken not to over-compress the breast and risk injury to the patient.

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6 Automatic exposure modes

Diamond's **Automatic Exposure Control** (**AEC**) system has three modes of operation:

- Auto kV exposure mode
- Auto Time exposure mode
- Manual exposure mode

Select the mode with the **Mode** select button. The light at the left of the button indicates the mode that is currently selected. An automatic exposure monitor will terminate the exposure in just 50ms if it calculates that a suitably exposed image cannot be achieved within the back-up time. Each AEC mode has 15 steps for density adjustment, where one step corresponds to a 10% decrease or increase (factory default). These steps may be adjusted by your service technician within a range of 5% to 20%.

Molybdenum or Rhodium filters can be selected either automatically or manually. Your service technician may activate the automatic filter selection (AutoFilter) upon request. If the Auto Filter function is inactive, then the filters are selected manually with a filter selection button. When Auto Filter mode is selected as 'ON', Diamond chooses the Molybdenum or Rhodium filter automatically, depending upon the breast thickness. When AutoFilter is enabled, the user can change the filter, but after the exposure AutoFilter will again select the used filter. The Aluminum filter is always selected manually at kV's of 35 and above. The Auto Filter feature is always disabled when Delta 32 unit is attached to Diamond.

WARNING!

Only authorized personnel may perform AEC programming.

6.1 Operation in Auto kV mode

In **Auto kV**-mode, Diamond determines the initial kV, based on the compression thickness. The user may change the initial kV and density settings before the exposure. During the exposure Diamond calculates appropriate kV, mAs/exposure time for the exposure.

Select the **Auto kV** mode with the **Mode**-key. A LED light indicates the selected option. Change the selected filter if necessary.

Fig 6.1. The mode display in Auto-kV mode

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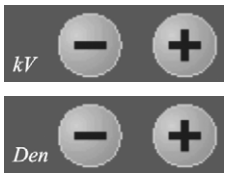
6.2 Operation in Auto Time mode



1 Select kV and Density. The exposure control system will determine the mAs/ correct exposure time when you make the exposure. A LED light indicates that the Auto Time mode has been selected.

2 Change the selected filter if necessary.

Fig 6.2. The mode display in Auto Time mode

NOTE!

If a correct optical density could not be reached, the Exposure monitor will terminate the exposure in 50 ms. If this occurs, change the film cassette and repeat the procedure, selecting a higher kV.

6.3 Operation in Manual mode

1 Select required kV and mAs. The system will select the correct exposure time (which depends on the selected mAs value).

2 Change the filter selection if necessary.

Fig 6.3. The mode display in Manual mode

6.3.1 Adjustment of the mAs-values in Manual mode

Select the mAs setting. Pressing the mAs+ button increases the mAs value and pressing mAs- button decreases the mAs value. The following mAs values may be selected.

2	3	4	5	6
8	10	12	16	20
25	32	40	50	63
80	100	125	150	175
200	250	300	350*	400*
450*	500*			

Table 6.1 Selection of mAs values

* not allowed in N.Y.

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6.4 AUTOMATIC COMPRESSION RELEASE (AUTO REL)

Automatic Compression Release is the default setting on Diamond and will release the compression paddle after each exposure or in the event of a power failure. You must decide whether or not you wish your Diamond to release compression automatically after compression. The automatic release is automatically switched off when Delta 32 or biopsy paddles are inserted. If a power failure occurs while 'Auto Rel' is switched off, the C-Arm remains compressed and compression paddle will not auto-release. The Auto Release can be manually switched off and on with a function key below Auto Rel text on Control Panel LCD-screen.

Fig 6.4. The control panel screen with Auto Rel-text

6.5 AUTOPOINT AEC DETECTORS

Diamond incorporates automatically or manually selectable detectors. Diamond's software control system can automatically determine the most appropriate AEC detector location for you at each exposure, depending upon the individual breast being examined. Each detector can also be selected manually by the user by simply pressing the relevant membrane button on the Detector Location Display that represents each detector. The semicircle and oval graphics printed on the Diamond's compression paddle indicate the size and location of each detector.

Testing the AEC

1 Expose at 28 kV and 40mm acrylic

2 Develop the film

3 Measure the O.D.

6.6 SELECTION OF MAS VALUE

During the exposure, the highest possible mA is automatically selected (within the range described in the mAs selection table) and this enables the minimum exposure time to be used. The AEC system terminates the exposure when the correct amount of radiation has reached the film. The exposure time range is from 0.02 sec. to 5 sec. when using the large focus (Bucky or cassette tunnel exposures), and from 0.04 sec. to 10 sec. when using the small focus (magnification exposures).

In manual exposure mode, the kV range is 20-39kV. In AEC mode the range for Bucky is 23-35kV and for the magnification tunnel 25-35 kV. In specimen mode, the kV range is 15-39kV.

Lowering mA for small breasts (from sw 1.02.1 and up)

When small breasts are examined, the O.D. may end up being too high. This may happen if exposure time saturates (exposure time shorter than 0.05s cannot be achieved with AEC), but the tube current can be lowered to 50%. Lower mA values can be used with Buckies and AEC mode only. If you want to use low mA mode for low thicknesses, have your Service Technician adjust preheat values for low mA for large focus (LF) and set

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the thickness limit below which Diamond automatically compensates the tube current for lower mA values.

6.7 MAXIMUM MAS/MA-VALUES

The maximum mAs-value is, however, limited by the selected kV and the maximum permitted time. The maximum mAs/mA values are shown in the table 6.2, Maximum mAs/mA values depending on kV and focus size.. Automatic mAs-selections are curtailed according to this table.

	MGX 0.3 focus	MGX 0.1 focus
kV	**mAs/mA**	**mAs/mA**
15	250/53	175/18
16	250/59	200/20
17	300/64	200/22
18	300/69	200/23
19	350/74	200/24
20	350/78	250/25
21	400/81	250/26
22	400/85	250/28
23	450/90	300/30
24	450/95	250/29
25	500/100	250/28
26	450/95	250/27
27	450/90	250/26
28	400/85	250/25
29	400/85	200/24
30	400/80	200/23
31	400/80	200/22
32	400/80	200/21
33	350/75	200/21
34	350/75	200/20
35	350/69	200/20
36	250/50	175/19
37	250/50	175/19
38	250/50	175/18
39	250/50	175/18

Table 6.2 Maximum mAs/mA values depending on kV and focus size.

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7 Menu options

Enter the control panel MENU screen by pressing the MENU&SET button. The MENU screen displays three options: **QA** (Quality Assurance), **MODES** and **SETUP**. In QA, the **Integrated Quality Control** (**IQC**) Test is performed. In MODES, pre-programmed modes or a specimen mode can be selected. In SETUP, system features are set.

The left-hand button proceeds to QA and the right-hand button enters the SETUP mode.

7.1 QA / Integrated Quality Control (IQC) test

Diamond has an **Integrated Quality Control** (**IQC**) test feature to keep the optical film densities the same even if the film processor conditions have changed.

Diamond can correct the AEC exposure times by up to ±40% after which the unit gives an error code and prompts for a check of the film processing system.

The IQC test is done with a phantom exposure. After the exposure the film is developed and its density checked with a densitometer. If the measured optical density is different to the current setting, the new value is entered in QA (Quality Assurance). The compression paddle drives up to the upper microswitch when you the enter the QA.

NOTE!

Diamond will always select AutoPoint AEC detector C1 for IQC exposure.

7.1.1 Performing the IQC test by using a phantom exposure

Entering the program

Press SET button. In the **MENU** screen, select **QA** (Quality Assurance).

NOTE!

The compression paddle drives automatically up to the upper microswitch and cannot be driven downwards for compression. This is to prevent exposure to a patient.

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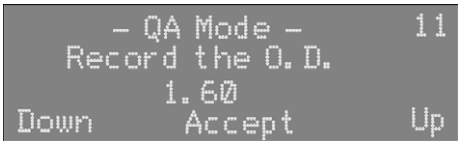
The following screen appears:



NOTE!

Do not change the O.D. value during this phase.

The actual thickness of the acrylic phantom is not important as long as the same phantom is always used for the IQC test and the measurement is taken at the same location on the film. If the user does not have any particular phantom to use and uses plain acrylic, thicknesses from 40mm to 60mm are recommended.

Positioning the acrylic phantom

Place the phantom onto the cassette holder (Bucky). Have the acrylic overlapping the front edge to make sure that no scattered radiation hits the detector.

If a mammography phantom is used (for example, RMI Model 156), place it flush with the cassette holder edge. This is necessary in order to visualize all objects in the phantom.

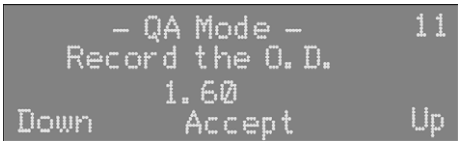
However, if the IQC results vary from procedure to procedure, check that the phantom does not allow direct radiation to enter the AEC detector; the phantom may have moved inwards from the cassette holder edge.

Performing the test

NOTE!

Diamond selects the filter and kV that has been programmed for IQC when the unit is switched on. Contact your service technician, if you want to use other values.

1 Place the phantom on the Bucky and press the Exposure button. The screen below remains in LCD display:



2 Develop the film.

3 Measure the O.D. on the film at the location of the used detector.

The screen displays the desired optical film density. Depending on the test result, different steps are taken next.

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A **No IQC adjustment necessary**

Accept

1 If the IQC value is correct, press the Accept key to exit the QA Mode.

Cancel

2 Press the Cancel key to return to normal operation.

B **IQC adjustment necessary**

If the test result shows a changed density reading, the current IQC value needs to be adjusted to the newly measured density value.

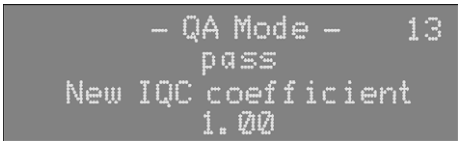
Down Up

1 Press the down and up keys until the newly measured density value is displayed.

NOTE!

If the test result differs considerably (max. 0.15-0.20, depending on country-specific regulations) from the required O.D. value (depending on country-specific regulations, e.g. 1.60), exit the test and check the film processor.

2 Press the middle button **Accept** to accept the value. The following screen appears:

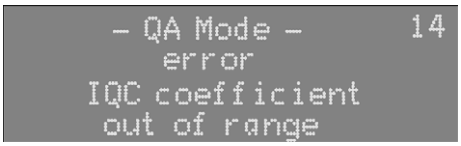


The screen display shows the new IQC coefficient with the remark **Pass** to indicate that it is within the acceptable range.

Cancel

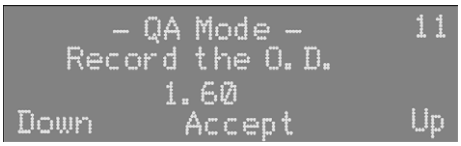
3 Press the Cancel key to return to normal operation.

If the IQC value is not within the acceptable range of density values, the following screen appears:

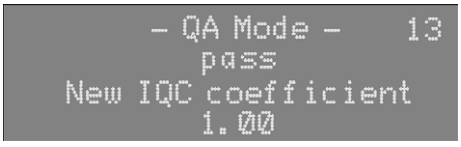


Down Up

4 In this case, enter a new density value with the down and up keys until the new value is displayed.



5 Press the Accept key to accept the value. The following screen appears:



The screen display shows the new density value with the message Pass, which indicates that it is within the acceptable range.

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6 Press the Cancel key to return to normal operation.

NOTE!

If the test result differs considerably (max. 0.15-0.20, depending on country-specific regulations) from the required O.D. value (depending on country-specific regulations, e.g. 1.60), exit the test and check the film processor.

7.2 OTHER MODES

7.2.1 Pre-Programmed/Specimen Modes

For the user convenience, Diamond software incorporates 4 pre-programmed modes, identifiable by name up 8 digits long for easy recall. Your service technician can set the following parameters for individual mode:

- density
- offset for initial kV in Auto kV mode
- target time 1/2
- name (max. 8 characters)
- Auto kV change limit
- AutoPoint coefficient

If the pre-programmed mode is renamed (max. 8 characters), the name of the mode will be displayed in left upper corner of the Control Panel LCD-screen.

A **Specimen** mode can be used to examine tissue that has been removed from the patient. In Specimen mode, kV values range 15 to 39 kV. When Specimen mode is selected, the LCD screen blinks and vertical movement is disabled.

WARNING!

Use Specimen mode to examine only the removed tissue, not the patient herself.

1 Select **MODES** from the menu screen:

The following screen appears:

2 Scroll up or down to the mode you want to select, then press Accept.

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7.2.2 Setup mode

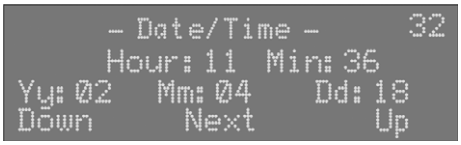
This mode enables feature programming.

1 Choose **SETUP** from the menu screen:

The following screen appears:

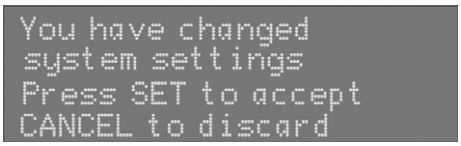
Scrolling the list, you find the options **Date/Time** and **Display**.

2 Set system date and time with the **Down**, **Next** and **Up** keys in the **Date/Time** screen:



3 Adjust brightness and contrast of the LCD-display with the **Down**, **Next** and **Up** keys in the **Display** screen:

The control panel display screen brightness and contrast can each be set in the range from 0 to 5. After completing the set-up, the system prompts you to confirm the changes:



4 Press the SET key to accept the changes, or cancel the changes with the Cancel key.

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8 Troubleshooting

8.1 No power indication

A Check that the power cord and control panel cable are connected.

B Check that the mains switch is switched on.

C Check the fuses or the circuit breaker.

D If the problems still persists, call your approved service center.

8.2 Ready light does not illuminate

Press the exposure button, and note the message text shown in the **LCD** display and refer to the “Check code guide” on the next page.

8.3 Grid lines

If the grid light on the control panel does not light up, check that the Bucky is properly attached on the cassette holder base. The exposure time is too short (shorter than 0.2 sec.). Reduce the kV to increase the exposure time.

8.4 Compression paddle stuck in upper position

The compression paddle has driven to its upper position at high speed after power failure. Release the compression paddle by turning the manual compression control handwheel counter-clockwise. In some circumstances, this may require some force to be exerted on the control wheel.

8.5 Error conditions

The Ready light indicates that every part of the unit is ready for exposure. If the light is not on within 50 seconds of the previous exposure or the ready light is blinking, an error condition has been detected.

Error conditions are indicated by a code on the LCD display.

Error codes are displayed on the LCD screen. Most error codes require a call to your service technician. If the error code includes an OK-text, press the middle function key (below the LCD) and then follow the procedures suggested by Diamond.

All possible conditions and the remedial action required are listed in table 8.1, Diamond error code guide.

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8.6 DIAMOND ERROR CODE GUIDE

These codes are currently in use. The sequence of error code is discontinuous because some error codes are reserved for future use.

Error code in LCD display	Reason for error	Corrective action
Er0002	Program check sum error (flash).	Call service.
Er0003	Program check sum error (BattRAM).	Check if exposure button cable is properly connected. Check physical condition of the cable (any broken strands etc.)
Er0011	Emergency button activated (pressed down).	Release emergency button.
Er0012	Tube Park safety clutch acts - tube obstacle.	Clear and try again. If problem persists, call service.
Er0013	Tube movement back up time reached.	Check for any visible obstacles for tube movement.
Er0014	Filter movement back up time reached.	Change another filter. If problem persists, call service.
Er0015	Collimator plate movement back up time reached.	Clear and try again. If problem persists, call service.
Er0022	Compression motor back up time reached.	Clear and try again. If problem persists, call service. Meanwhile, compress manually.
Er0023	Compression thickness measurement error.	Clear and try again. If problem persists, call service.
Er0024	Compression force measurement failure. Inhibit compression down.	If problem persists, call service. Compress manually.
Er0027	Overflow in Auto Time-or Auto kV-mode.	kV too low. Try with higher kV values.
Er0029	Underflow in Auto Time or Auto kV-mode	kV too high. Try with lower kV values.
Er0033	Cassette tray back up time reached.	Clear and try again. If problem persists, call service.

Table 8.1 Diamond error code guide

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Error code in LCD display	Reason for error	Corrective action
Er0034	Cassette not changed.	Change cassette. Try also with another cassette.
Er0035	Cassette opto sensor failure.	Check cassette opto sensors. Reduce lightning in Bucky area.
Er0037	Grid error during/prior to exposure. Displayed after exposure, if exposure started.	Re-attach Bucky. Try also with another Bucky.
Er0038	Cassette holder not attached when trying to expose. Inhibit exposure.	Attach cassette holder.
Er0041	Stereo not in 0 degrees when exposing.	With Delta 32, drive the stereo arm first to left and right, then back to 0° position. If you have no Delta 32, call service.
Er0042	Stereo movement error.	Check that Delta 32 unit properly attached.
Er0043	Vertical movement motor back up time reached.	Clear and try again. If problem persists, call service.
Er0045	ECS motor back up time reached.	Clear and try again. If problem persists, call service.
Er0048	C-Arm rotation back up time reached.	Clear and try again. If problem persists, call service.
Er0051	C-Arm angle measurement failure. Drive to predefined angles not allowed.	Clear and try again. If problem persists, call service.
Er0053	General communication error with internal electronics.	Clear and try again. If problem persists, call service.
Er0054	External communication error with serial port. Buffer overflow.	Clear and try again. If problem persists, call service.
Er0055	External communication error with RS232.	Clear and try again. If problem persists, call service.
Er0057	mA failure.	Clear and try again. If problem persists, call service.
Er0058	Anode start failure	Clear and try again. If problem persists, call service.

Table 8.1 Diamond error code guide

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Error code in LCD display	Reason for error	Corrective action
Er0059	Anode run failure.	Clear and try again. If problem persists, call service.
Er0060	Exposure button released during exposure.	Load new film and expose. Hold exposure button down until the audio signal ends.
Er0062	Generator failure. kV not OK.	Clear and try again. If problem persists, call service.
Er0063	Line voltage low.	Have an electrician check the voltage of the electric outlet. If it is strong and stable enough, then call service for further actions.
Er0064	Cassette missing.	Insert a cassette and try also with another type.
Er0065	Exposure time exceeds limit (too long/too short).	Increase/decrease kV values and try again. If problem persists, call service.
Er0066	Movement button or switch exposure button pressed during movement or start-up, function not allowed.	Clear and try again. If problem persists, call service.
Er0067	Device not ready for exposure.	Clear and try again. If problem persists, call service.
Er0068	Delta 32 PC refused to receive exposure.	Clear and try again. If problem persists, call service.
Er0069	Delta 32 PC connection time-out.	Clear and try again. If problem persists, call service.
Er0070	Error in stereo motor pulse measuring.	Clear and try again. If problem persists, call service.
Er0071	Tube head heat limit exceeded.	Wait and let cool down enough. Remaining cooling time indicated in timer screen. Clear and try again. If problem persists, call service.
Er0072	Side collimator failure.	Clear and try again. If problem persists, call service.
Er0074	Internal communication error. AEC Board not answering. Cable broken.	Clear and try again. If problem persists, call service.

Table 8.1 Diamond error code guide

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Error code in LCD display	Reason for error	Corrective action
Er0075	Internal communication error. Compression Board not answering.	Clear and try again. If problem persists, call service.
Er0076	Internal communication error. Stereo Board not answering.	Clear and try again. If problem persists, call service.
Er0077	Internal communication error. Collimator Board not answering.	Clear and try again. If problem persists, call service.
Er0078	Internal communication error. Control Panel not answering.	Clear and try again. If problem persists, call service.
Er0080	Stereo movement back up time reached.	Clear and try again. If problem persists, call service.
Er0081	Cassette in rear position.	Clear and continue use. Should cassette not move to the front position, drive it there manually.
Er0082	1) C-Arm rotation with the tube head in rear position disabled when vertical down C-arm angle over 120°. 2) Z-movement down blocked when the C-arm angle exceeds 122°.	1) For C-Arm angles over 120°, drive the tube head to the front position. For lowest Z-position, drive drive the tube head is in front position. 2) Drive the C-arm to less than 122° (the tube head must be in front position).
Er0084	Transmit buffer overflow in Supervisor software.	Clear and try again. If problem persists, call service. Release compression manually.
Er0087	Movement inhibited during compression.	Release compression and try again.
Er0089	C-Arm center limit not found.	Drive manually in the center. If problem persists, call service.
Er0090	Tube not in front position.	Remove Delta 32 or biopsy paddles to enable tube head AutoDrive.
Er0091	Z-movement disabled in Specimen mode.	Clear and continue. If a patient is to be examined, exit the Specimen mode.

Table 8.1 Diamond error code guide

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9 System maintenance

9.1 Cleaning of the Diamond unit

WARNING!

Before cleaning and disinfecting, disconnect all power from the equipment.

WARNING!

Do not allow liquids to enter the unit.

ALL parts of the unit that come in contact with the patient must be cleaned and disinfected prior to each examination. Cleaning of the unit is especially important after biopsy procedures (refer to biopsy device user manual for cleaning procedure).

The standard hospital regimen for disinfection should be followed, with the following qualifications:

DO NOT clean surfaces on parts, which come into contact with the patient (i.e., face shield, cassette holders, Bucky devices, compression paddles) with solvent-based cleaners (containing benzene, alcohol, or stain removers).

DO NOT use extra-strength or abrasive cleaners, polishes, or waxes on parts that come into contact with the patient.

Proprietary disinfectant solutions meeting the above limitations are suitable, provided that the manufacturer's instructions are stringently followed. DO NOT immerse the Bucky in disinfectant solution.

As a general rule, disinfectant sprays may not be used directly. The mist generated by spraying may penetrate into the unit and damage electronic components. To use a disinfectant agent in spray form, first apply the agent to a clean cloth or pad, and then use the pad to apply the agent to the surface requiring disinfectant.

For general cleaning, use a non-lint cloth dampened with water, or a lukewarm, diluted aqueous solution of household dishwasher liquid.

9.2 Care

Handle the plastic accessories carefully, and inspect them frequently. If they begin to crack, discontinue their use and replace them.

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9.3 OPERATORS MAINTENANCE SCHEDULE

For the safe and proper operation of the unit, the following inspections must be performed monthly (or daily or weekly if so indicated) by the operator of the equipment.

Monthly check-up	Procedure
Visual Exposure Indicator	Confirm that the exposure indicator light stays on for the length of the exposure.
Audible Exposure Indicator	Confirm that the buzzer stays on for the length of the exposure.
Exposure Switch	Confirm that the exposure switch requires continuous pressing to maintain the exposure and that releasing of the switch terminates the exposure and that the timer display indicates “Rel”.
Warning and Indicator Labels	Inspect and confirm that all warning labels and embossed, painted or other wearable labels have not been defaced or worn and that they are legible.
Automatic Exposure Control (AEC)	Confirm that the autoexp light illuminates when AEC is selected. A daily QA check is recommended. Software monitors the status of each detector and prevents an exposure with a faulty detector.
Vertical Movement	Check that the carriage moves smoothly and in both directions.
Compression force	Check that the compression force has not changed.
Compression release when power failure	Check that the compression paddle drives up for approximately 5 seconds when the mains voltage is disconnected.
Rotation Movement and angle display	Check that the C-Arm moves smoothly in all positions. Check that the displayed angle corresponds to the selected angle. Also check that +/- 15° motorized stereo angulation movement is functioning correctly.
Control Panel	Check that all buttons on the control panel are functioning and check that all lights and display segments function immediately after turning the main power on.
Compression thickness display check	Place a 60 mm acrylic block on the cassette holder. Drive the compression paddle down against the acrylic blocks. Check that the thickness display indicates 6.0 cm. If not, call for service.
X-ray field light check	Switch on the x-ray field illumination light and check that it covers the imaging area.

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Monthly check-up	Procedure
Compression paddles	Once a week, check all compression paddles for any cracks or broken surfaces.
Strange sounds	Pay attention to any strange sounds that your unit may make inform your service technician about these immediately. If you have any doubts about the correct safe operation of the unit, switch it off and do not use it until you can it checked by an GE-approved service technician.
Manual decompression	Compress against an object at 200N and verify that you can decompress manually with hand wheels.

CAUTION!

If you suspect any electromagnetic interference affecting or caused by the unit, call service.

9.4 PREVENTIVE MAINTENANCE SCHEDULE

The following inspections must be scheduled by the user. Only authorized and trained service technicians are allowed to carry out the maintenance on this equipment. The manufacturer can supply at request necessary documents to an GE-approved service technician for repair of such parts that the manufacturer has indicated to be repairable.

Once a year	Procedure/Section in Diamond Installation Instructions (86501-IMG)
kV/mAs/preheat tests	Perform test 7.2.10.
X-ray and light fields	Perform tests 7.2.2 and 7.2.3.
AEC adjustment	Perform test 7.3.1.
Safety ground	Verify that the metal parts of the unit are connected to protective ground.
Oil leaks	Check that the high voltage unit and the tube housing do not leak oil.
Anode run voltage	Perform test 6.3.
Compression force	Perform test 7.2.8.
Interlock system	Check that exposures are inhibited if the diaphragm, cassette holder or the cassette is not installed. Check the error codes.
Clean the High Voltage Connections and grease with clean grease for example DowCorning #4.	
Lubricate the counterweight wires with a light coat of “STP” or “CRC”. Do not apply de-greasers or cleaners. Replace if broken strands are found. Recommended wire replacement interval is 5 years.	
Tighten ground connections. Inspect crimps, connections and cables for wear or breakage.	

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Once a year	Procedure/Section in Diamond Installation Instructions (86501-IMG)
Check for the operation of the C-Arm gear. Lubricate, if necessary.	
Check the collimator and filter mechanism and movement.	
Inspect the floor fixing points to ensure the secure and safe fixing of the support base plate of the unit.	
Check the stereo drive mechanism.	
Check Tube Park alignment.	
Update the tube efficiency software parameters.	
Remove debris from the cassette loading mechanism and lubricate it.	
Apply grease annually on Stereo drive mechanism if Delta 32 is used with Diamond.	
Emergency buttons	Verify that all electronically controled movements (vertical, c-arm rotation, compression) are disabled when emergency button is pressed down. All motorized movements should stop. Release the emergency stop button, switch on the unit once again and then repeat the test using the emergency stop button on the opposite side of the unit. Finally, verify that normal operation of the unit is restored once the button is back in normal position.

9.5 QUALITY CONTROL CHECK

If the performance of the unit has changed, please contact your local distributor.

Distributor:				
Contact person:			Tel:	
Diamond serial number *):		Installation date:		
Last maintenance performed:				
Exposure counter number:				
Last maintenance performed:				
Exposure counter number:				

*) The serial number is printed on a label attached to the rear cover of the unit.

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TEST	FREQUENCY	TOOL(S)	PERFORMED BY
Film Processor	Daily	Thermometer Densitometer Sensitometer	Radiographer/ Technologist
Image Quality	Weekly	RMI 156D Phantom	Radiographer/ Technologist Physician
Phototimer Reproducibility	Monthly Daily (mobile installation*)	Acrylic phantom	Radiographer/ Technologist Physician
Film/Screen Contact	Semi-annually	Contact test tool	Physicist or Service Technician
kVp	Semi-annually	Dynalyzer	Physicist
Dose/Patient Exposure	Semi-annually	Ion Chamber or semi-conductor detector	Physicist
Half-Value Layer (HVL)	Semi-annually	Aluminum HVL set with Ion Chamber or semi-conductor detector	Physicist
mAs (mA)	Semi-annually	Dynalyzer (mAs meter)	Physicist or Service Technician
mAs Linearity	Semi-annually	Ion Chamber (Digital) or semi-conductor detector	Physicist or Service Technician
Compression	Semi-annually	Scale	Radiographer/ Technologist
Exposure Reproducibility (mR/mAs)	Annually	Ion Chamber or semi-conductor detector	Physicist or Service Technician
Line pair resolution	Annually	Bar Pattern	Physicist

* With mobile installations without development of films (i.e., film changer), check with familiar phantom that kV and mAs values are OK.

CAUTION!

Refer to local regulations and instructions concerning the testing of the unit.

If the unit does not meet the manufacturer´s specifications, regardless of proper maintenance and repair, the operating life of the unit has come to an end. As the used X-ray tube and oil, high voltage unit, all electronic boards and parts of lead in collimator and under the AEC detectors are toxic waste, refer to country-specific disposal instructions.

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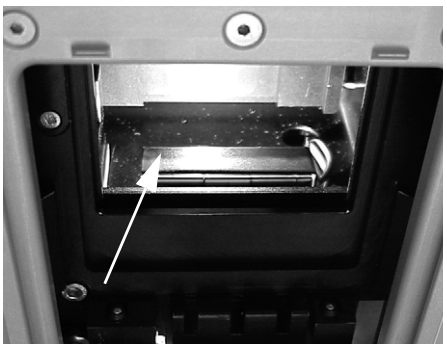
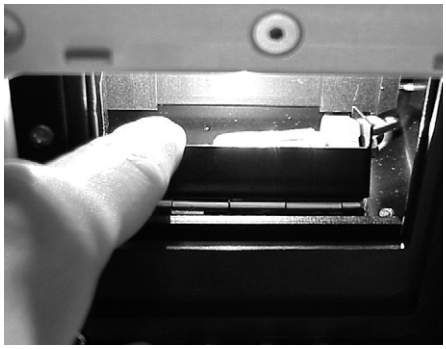
9.6 REPLACEMENT OF THE LIGHT FIELD BULB

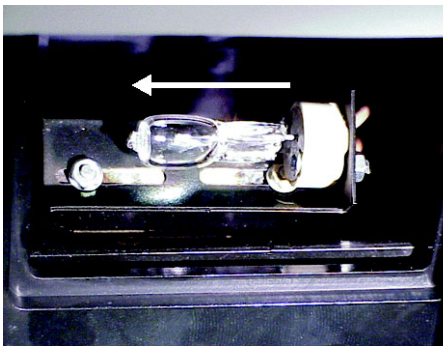
1 Turn the unit off and leave it for a while to allow the bulb to cool down.

2 Slide the lamp support plate open.

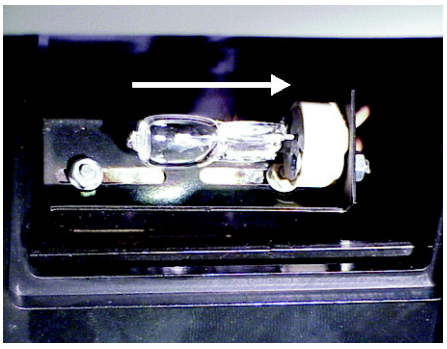




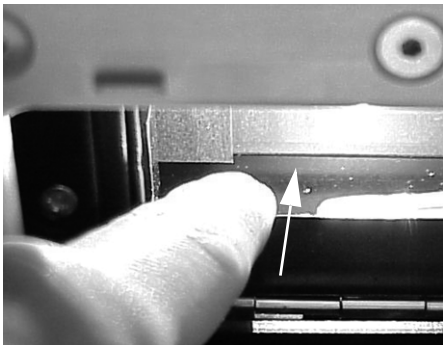
3 When you see the old bulb lamp, pull it out.



4 Insert a new bulb. Avoid touching the bulb with your fingers. Use a protective plastic bag (around the bulb, dependent on the bulb manufacturer) or cotton gloves.



5 Slide the lamp support plate back to normal position.



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10 Specifications

System specifications for Diamond, model MGX 2000	
Manufacturer	GE Healthcare Finland Oy Kuortaneenkatu 2, FIN-00510 Helsinki, Finland
Manufacturer's quality system according to	ISO9001
Manufacturer's environmental management system according to	ISO14001
General	Medical electrical equipment
Model	MGX 2000
Power supply	Mains plug connection, 1-phase (line, neutral and protective ground, or L1, L2 and protective ground)
Apparent resistance of supply mains	0.75Ω
Rated voltage	230 VAC ±10%, single phase, 50/60 Hz 16 A slow blow fuse in power outlet

NOTE!

The Diamond is a cord-connected device, delivered without a plug (in some markets). Depending upon local electrical code requirements, it may be either hard-wired or plugged into an outlet. Please consult your electrician to determine the requirements, and if necessary to provide a plug which matches your outlet.

Line Regulation:	± 2% (full load)
Branch Circuit:	dedicated run 20A, 2-pole circuit breaker L1/L2 (10 AWG) Outlet per local electrical code requirements or NEMA L6-20
Grounding:	0V potential (earth), continuous wire run (not conduit)
Rated current	20 A Momentary (during exposure) 300 mA long term (otherwise)
Rated input power	4.6 kVA
IEC safety class	I

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System specifications for Diamond, model MGX 2000	
IEC applied part type	B
Enclosure	IP 20
Weight	350 kg (771 lbs.)
Height	1.9 m (6 1/4 ft)
Operation mode	Continuous operation with intermittent loading
Radiation intensity	Typical range 1000-1200mR/ 100mA at 28kV

Environmental specifications	
Operating conditions	+10°C...+40°C Non condensing (maximum humidity 90%)
Storage and transportation	(+0°C...+35°C)
Humidity	10%...100%
Pressure	500 mbar - 1060 mbar

Generator	
Manufacturer	GE Healthcare Finland Oy
Type	MGHV-300
Frequency	40 - 100 kHz
Power	Max. 2.6 kW
kV range	15 - 39 kV, in 1 kV increments
Accuracy	± 1.5 kV
kV ripple	< 4%
mA range	Focus 0.3 mm 50 - 100 mA Focus 0.3 mm 25 - 50 mA (low mA mode) Focus 0.1 mm 18 - 30 mA (- tube current reduced with small breast thickness)
Maximum mA output	Focus 0.3 mm 150 mA Focus 0.1 mm 45 mA

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Generator	
mAs range	Focus 0.3 mm 2 - 500 mAs: Tolerance: mAs ≤ 40: ± 4 mAs mAs > 40: ± 10%
	Focus 0.1 mm 4 - 300 mAs Tolerance: mAs ≤ 40: ± 4 mAs mAs > 40: ±10%
Time range	Focus 0.3 mm 0.02 - 5 s Focus 0.1 mm 0.04 - 10 s Tolerance: ± 0.10 + instrument inaccuracy

Tube loading chart for Diamond X-ray tube (M113SP)					
kV	**M113SP mA(SF)**	**M113SP mA(LF)**	**kV**	**M113SP mA(SF)**	**M113SP mA(LF)**
15	18	53	28	25	85
16	20	59	29	24	85
17	22	64	30	23	80
18	23	69	31	22	80
19	24	74	32	21	80
20	25	78	33	21	75
21	26	81	34	20	75
22	28	85	35	20	69
23	30	90	36	19	50
24	29	95	37	19	50
25	28	100	38	18	50
26	27	95	39	18	50
27	26	90			

SF = Small focus, LF = large focus

Time range with loading factors shown above:

- Focus 0.3 0.02 - 5.0 sec.
- Focus 0.1 0.04 - 10.0 sec.

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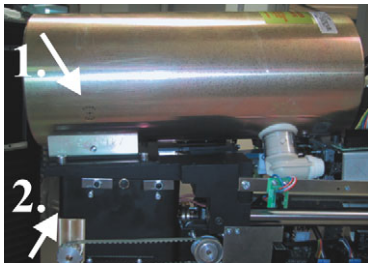
Automatic Exposure Control (AEC)	
Solid state 15 step density selector	
Operating range	for large focus 23 - 35 kV for small focus 25 - 35 kV
Nominal shortest irradiation time	60 msec.

X-RAY TUBE	Diamond (Varian M113SP in B112 housing)
Anode type	Rotating dual-angle anode
Anode heat capacity	300,000 HU
Target material	Molybdenum, niobium doped
Anode rotation speed	3000rpm(50Hz)/3600rpm(60Hz)
Focal spot sizes	M113SP 0.1, 0.3 (IEC60336)
Port material	beryllium
Reference axis	42 mm (M113SP) from chest wall edge (tube angle 4°)

1 Focal spot is marked in the front part of the tube head assembly.

2 The collimator label is at the front end of the tube head assembly.



Diamond Filtration	
Molybdenum Rhodium Aluminum	0.025 mm 0.025 mm 0.50 mm

Positioning	
Source to Image Distance (SID)	660 mm (26”)
Movement of the motorized, dual-speed carriage	
Rotation Vertical	±185° 760 mm (30”)
The cassette holder vertical movement range is 68 cm - 144 cm above finished floor level (27” - 57”) with the C-Arm in the upright position (0°) and 79 cm - 156 cm (31” - 61”) with C-Arm rotated in the lateral (90°) position.	

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Compression	
motorized manual	Max 200N Max 270N±20N
Foot pedal protection classification	IPX1

Recording systems	
Bucky	for 18 x 24 and 24 x 30cm film
Magnification	for 18 x 24 cm film 1.6, 1.8 & 2.0 exposed size 10 x 24
Stereotactic device	Delta 32 digital ccd-camera

Display accuracy	
Compression force	± 20N
Compression thickness	± 1cm
C-Arm angle	± 2°
mGy display	± 30%
For mGy display accuracy, refer to: "Spectral Dependence of Glandular Tissue dose in Screen-Film Mammography" Wu Xizeng, Wu X, Barnes Gary T, Tucker Douglas M, Radiology 1991; 179:143-148 "Normalized Average Glandular dose in Molybdenum Target- Rhodium Filter and Rhodium Target -Rhodium filter Mammography" Wu Xizeng, Wu X, Gingold Eric L, Barnes Gary T, Tucker Douglas M, Radiology 1994; 193:83-89	

Correspondence between X-ray field and image reception area	
Chest wall	0...+3 mm
Other walls	+1...+5 mm
Correspondence between collimator light field and X-ray field	≤ 5 mm any wall

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Collimator	
Type	MGB 600
Filtration	0 mm Al
Electrical input	34 VAC (for half-step motors) 9-14 VDC (for 12 VDC lamp)
Lamp type	HLX (halogen), 12V, 50W

Radiation field	
Maximum radiation field	24x30 cm

Attenuation equivalent	
Bucky, cassette tunnel or magnification tunnel	≤ 0.25 mm Al (Total of all layers)

Anti-scatter grid	
Line pairs	36 l/cm
Grid ratio	5:1

ROC Grid	
Line pairs	36 l/cm
Grid ratio	equal to 6:1

Measurement criteria for exposure time	
Exposure time	Consists of beginning and ending points as measured by a calibrated x-ray monitor at 70% of the peak radiation waveform.
kV	The high voltage mean value received after measurement with a calibrated x-ray monitor.
mAs	The resistance value divided by voltage. A calibrated x-ray monitor measures the voltage over feedback resistor and provides a mAs value.
The **nominal x-ray voltage** 39kV is obtained at highest tube current 50 mA.	

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The **nominal tube current** 50 mA is obtained at the highest tube voltage 39kV.
The **highest tube current** 100 mA is obtained at 25 kV tube voltage.
The **highest electric power** is obtained at 32kV tube voltage and 80 mA tube current.
The **nominal electric power** of 2.4 kW is obtained, when loading time is 0.1s, tube current at 80 mA and x-ray tube voltage at 30 kV.

Fuses	
Power Board 85020, F1,2	Fuse 5x20 mm 4AT, IEC 127-2/3
F3	Fuse 6.3x32 mm, 15ASB 250V
F4	Fuse 5x20 mm 0.8AT, IEC127-2/3
F5	Fuse 13/32" 20AF 600VAC (Bussmann KTK-20)
AMD 32305, F1	Fuse 6.3x32 mm 10AT 250V

Diamond fuses used by Delta 32	
On PCB located in the bottom-part plate of the C-Arm.	
Fuse Board 33615, F5	Fuse 1 pc 6x32 mm 1,25AT 250V UL
F3	Fuse 1 pc 6x32 mm 0,8AT 250V UL
F1,2,4	Fuse 3 pcs 6x32 mm 0,5AT 250V UL
In the carriage next to the transformers: D32 Fuse Plate 82685	
F1,2	Fuse 2 pcs, 6X32 mm 0,3AD 250 UL 248-14

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10.1 ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

The Diamond is suitable for use in the specified electromagnetic environment. The purchaser or user of the Diamond should assure that it is used in an electromagnetic environment as described below:		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Radio-Frequency Emissions CISPR11	Group 1	The Diamond uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR11	Class B	The Diamond is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	The Diamond is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	The Diamond is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 10.1 Electromagnetic emissions IEC 60601-1-2

The Diamond is suitable for use in the specified electromagnetic environment. The purchaser or user of the Diamond should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality is that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality is that of a typical commercial and/or hospital environment.

Table 10.2 Electromagnetic immunity IEC 60601-1-2

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The Diamond is suitable for use in the specified electromagnetic environment. The purchaser or user of the Diamond should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_n for 5 sec	0 % U_n for 5 sec	Mains power quality is that of a typical commercial and/or hospital environment. If the user of the Diamond requires continued operation during power mains interruptions, it is recommended that the Diamond be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/ or hospital environment.
NOTE: U_n is the a.c. mains voltage prior to application of the test level.			

Table 10.2 Electromagnetic immunity IEC 60601-1-2

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The Diamond is suitable for use in the specified electromagnetic environment. The purchaser or user of the Diamond should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6 Radiated RFIEC 61000-4-3	3 V150 kHz to 80 MHz 3 V/m80 MHz to 2,5 GHz	[V_1] 3 V [E_1] 3 V/m	Portable and mobile RF communications equipment are used no closer to any part of the Diamond, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:

*Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe the Diamond to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Diamond.

**Over the frequency range 150 kHz to 80 MHz, field strengths are less than [V_1] V/m.

The Recommended Separation Distances are listed in the next table.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 10.3 RF immunity of non-life-support equipment or system IEC 60601-1-2

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Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
Frequency of Transmitter	**150KHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
Equation	$d = [\frac{3,5}{V_1}]\sqrt{P}$	$d = [\frac{3,5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
Rated Maximum Output Power of Transmitter (watts)	**Separation Distance (meters)**	**Separation Distance (meters)**	**Separation Distance (meters)**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

Table 10.4 Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2

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11 User's Statement Of Model Diamond

Radiation Leakage Technique Factors:

The maximum-rated peak tube potential is 39 kVp and the maximum-rated continuous tube current is 4.0 mA (Duty cycle 1:12) for the maximum-rated peak tube potential at a large focal spot. The maximum-rated peak tube potential is 35 kVp and the maximum-rated continuous tube current is 4.5 mA (Duty cycle 1:3) for the maximum-rated peak tube potential at a small focal spot.

Beam Limiting Device/Tube Housing Assembly Compatibility:

The tube housing assembly is compatible with the interchangeable plate collimator assembly, which is an integral part of the tube head and can only be used with the tube housing assembly.

Equipment Statement for Tube Housing Assembly:

Maximum operating voltage:

35 kVp-effective focal spot 0.3 mm for a large spot 0.1 mm for a small focal spot.

X-ray tube:

Varian M113SP 0.3/0.1. For additional information, refer to tube specification sheets.

Operating parameters

Maximum Deviation of Peak Tube Potential from Indicated Value:

± 1.5 kV + instrumentation inaccuracies (1.5% of the reading + 600 V) as measured by a calibrated Dynalyzer

Maximum Deviation of Tube Current-Exposure time from Indicated Value**:**

± 4 mAs for mAs values less than or equal to 40 mAs ±10% for mAs values greater than 40 mAs

Maximum Deviation of Timer from Indicated Value**:**

± 0.1 second + instrumentation inaccuracies (0.5% of the reading + 0.25 msec.) as measured by a calibrated Dynalyzer

Power Supply Requirements**:**

Line voltage 230 VAC ± 10%, 50/60 Hz, single phase. Operating Voltage Range 207-253 VAC

Automatic regulation for all voltages within Operating Voltage Range.

Maximum Line Current:

Maximum line current during exposure is 30 A at technique factors 25 kVp and 100 mA. The system line circuit breaker is 15 A because the maximum line current of 30 A is only during short peaks during the exposure.

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General Output Rating and Duty Cycle:

At 230 VAC nominal:

Large Focal Spot 100 mA at 25 kV, 70 mA at 35 kV
Small Focal Spot 30 mA at 23 kV, 20 mA at 35 kV

Exposures are automatically limited if the tube or housing heat capacity counter is activated.

Tube protection counter:

Anode:
Heating = kV x mAs = Joule (increased only during exposures)
Cooling = 30 Joule / sec. (decreased continuously)

Housing:
Heating = kV x mAs = Joule (increased only during exposures)
Cooling = (decreased continuously) refer to the diagram in Chapter 12.3, Housing heating and cooling curves

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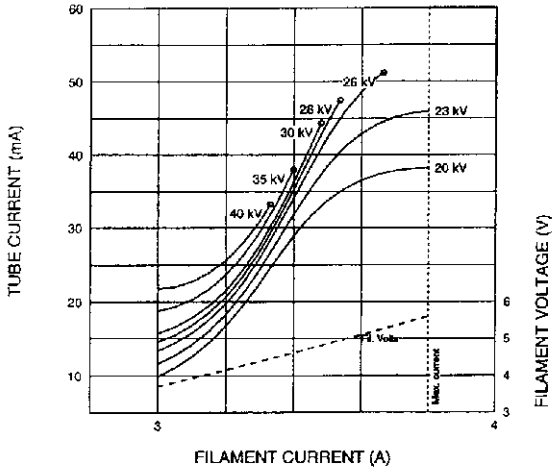
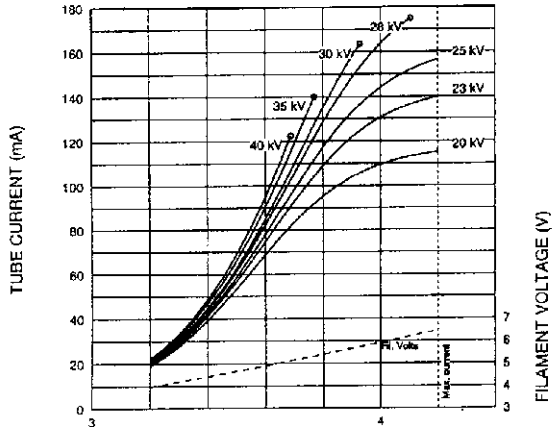
12 Diamond X-ray tube data sheets

Various tube charts and markings are included in the latest revision of 5708, M113SP Rotating Anode Tube by Varian Medical Systems.

12.1 M113SP FILAMENT EMISSION CHARTS

3 Ø Full Wave





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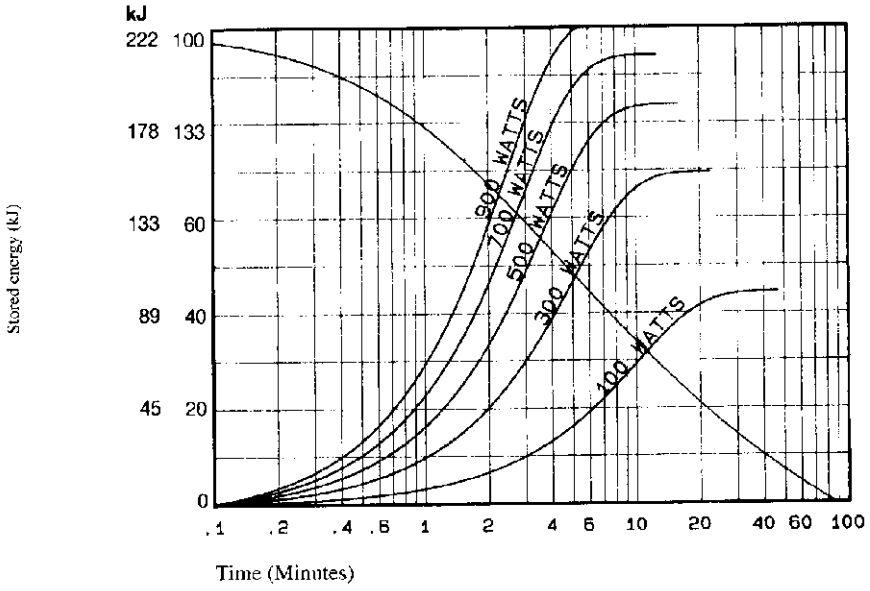
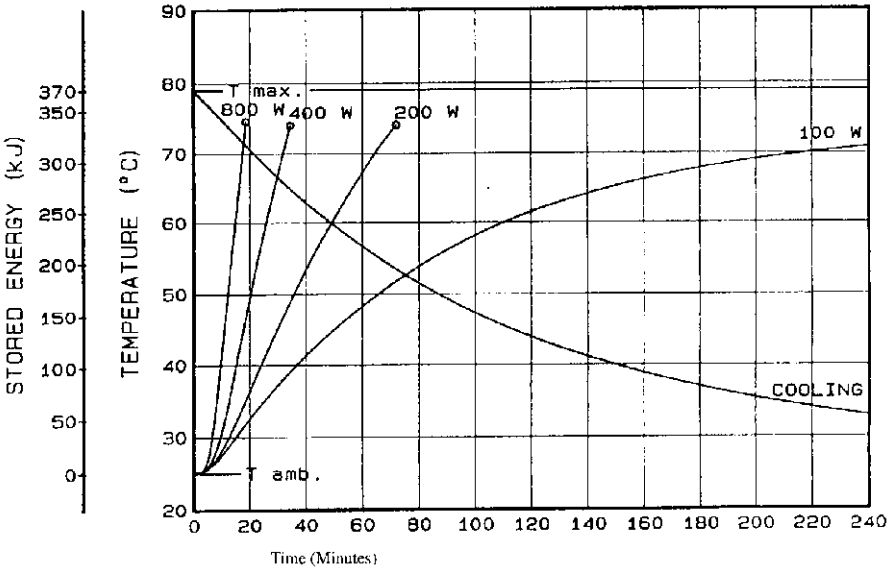
12.2 ANODE HEATING AND COOLING CURVES



12.3 HOUSING HEATING AND COOLING CURVES



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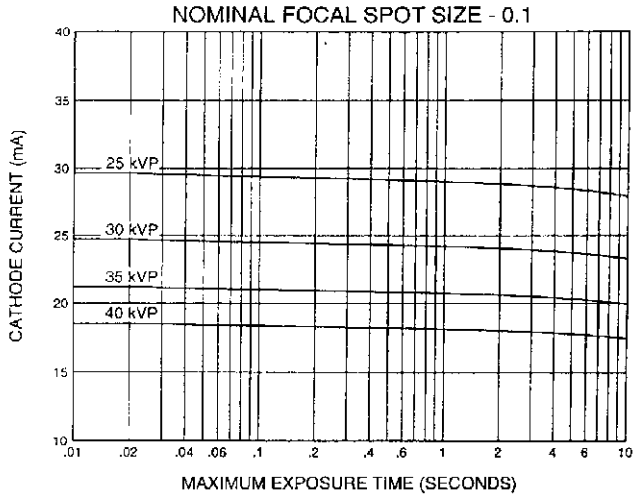
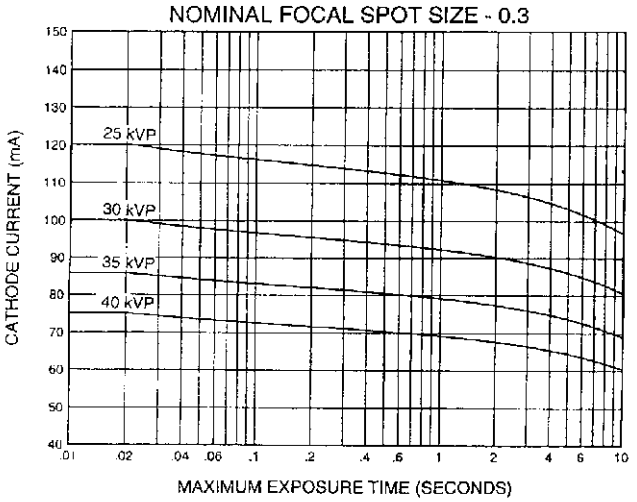
12.4 SINGLE LOAD RATINGS

12.4.1 Constant Potential 50 Hz



0.1 ▣

M113SP RADIO 01 50 HZ



0.3 ■

M113SP RADIO 03 50 HZ

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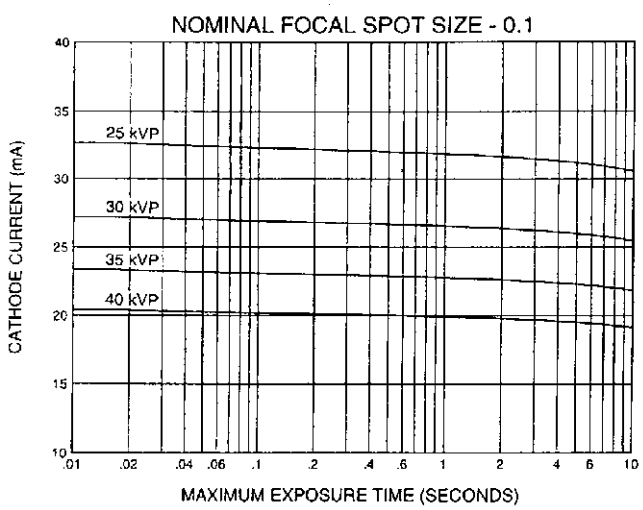
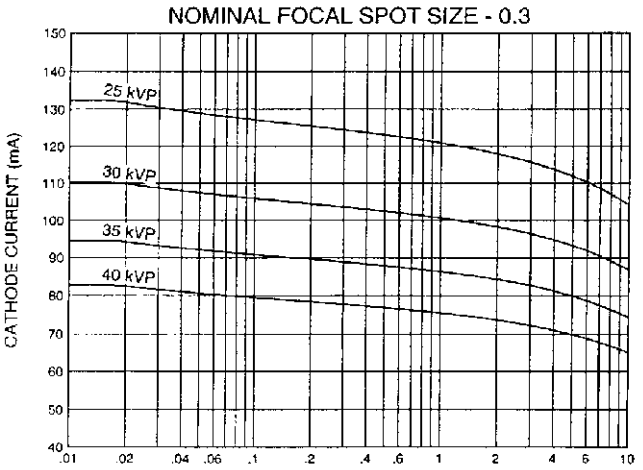
12.4.2 Constant Potential 60 Hz



0.1 ▣

M113SP RADIO 01 60 HZ



0.3 ■

M113SP RADIO 03 60 HZ

12.5 DESCRIPTION

The M113SP rotating anode X-ray tube is a 39 kVp VARIAN insert tube with 0.1 mm and 0.3 mm focal spot combination and 77 mm diameter bi-angular (10°/16°) Molybdenum anode disc, cathode grounded.

The M113SP metal center section X-ray tube is for use in Mammography systems. The use of a metal center section tube eliminates arcing due to metal deposition on glass and allows use of a beryllium window in the insert for minimum inherent filtration.

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12.6 GENERAL DATA

Maximum Peak Voltage:	39 kV (Anode to Ground)
Nominal Focal Spot Size:	Small 0.1 mm (Refer to General Information Section for Focal Spot Measurement Method) Large 0.3 mm
Maximum Anode Load:	3-phase, 180Hz, 0.1 second
Small Focal Spot:	1320 W
Large Focal Spot:	2.6 kW
Anode Disc Construction:	Molybdenum Alloy
Anode Disc Diameter:	77 mm
Anode Disc Target Angle:	M113SP (LF/SF) 16/10
Anode Heat Storage:	300 kHU
Maximum Anode Cooling Rate:	60,000 HU/minute
Inherent Filtration:	0.0 mm Alum. Equiv. 0.76 mm Beryllium
U/L Approved:	Yes

12.7 B-112 HOUSING

Class:	I
Type:	B
Maximum Peak Voltage:	52 kV
Anode to Ground:	52 kV
Cathode to Ground:	0 kV
Housing Heat Storage Capacity:	370 KJ (500 kHU)
Housing Cooling Rate:	100 Watts (135HU/sec.)
Weight:	10.2 kg (22.5 lbs)
Length:	33 cm (13”)
Diameter:	13.8 cm (5.44”)
Focal Spot - Port Spacing:	Small 47.0mm ± 1mm Large 41.4 ± 1mm
High Voltage Cable, Special Design (Non-Federal Standard):	55 kV Rating
Acoustic noise:	50dB Max. (A-weighted) at 30 cm
Leakage Technique Factor M113SP:	52 kV, 2mA
Leakage Technique Factor B112:	55 kV, 4mA
Minimum Ambient temperature for storage & transportation:	-9°C (16°F)
Maximum Operation Temperature:	+40°C (+104°F)

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Low Voltage Cable:	
Pin Position	Function
1	Phase Shift
2	Phase
3	Common
4	Housing Ground
5	Grid
6	Not used
7	Small Filament
8	Filament Common
9	Large Filament

12.8 FILAMENTS

Focal spot	Volts	Amperes
0.1	3.8 - 7.3	3.0 - 4.8
0.3	6.0 - 10.5	3.6 - 5.2

12.9 STATOR 50/60 HZ

Starting	115 V	230 V
Amperes	4	8
Seconds to start	1	0.5
Duty	Intermittent	Intermittent

Running	45 V	90 V
Amperes	1.4 - 2.0	1.4 - 2.0
Duty	Continuous	Continuous

PHASE SHIFT CAPACITOR: 30 Microfarad

Safety: Thermal Switch

- Connected in series with stator common wire
- Opens at 79.4°C ± 3.9°C (175°F ± 7°F)
- Closes at 68.3°C ± 3.9°C (155°F ± 7°F)

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12.10 INHERENT FILTRATION

Inherent filtration of the insert is 0 mm Aluminum equivalent. For operation of the X-ray tube to 39 kV, a minimum of 0.5mm Aluminum equivalent must be added to the X-ray beam.

12.11 RAYPROOFING

Stray radiation complies with the requirements of 21 CFR, Subchapter J for medical diagnostic-type protective X-ray tube housings.

12.12 FOCAL SPOT MEASUREMENT METHOD

M113SP small focus:

Measured at 25kV, 20mA with one degree star pattern or a slit focal. Maximum focal spot size = 0.15W x 0.15L (mm).

M113SP large focus:

Measured at 25kV, 80mA with one degree star pattern or a slit focal. Maximum focal spot size = 0.45W x 0.58L (mm).

Specification of the maximum focal spot size limits must be performed on the techniques listed above.

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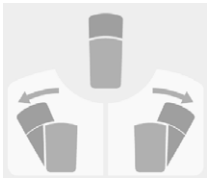
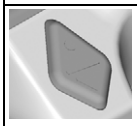
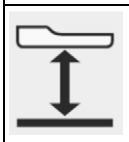
14 Graphical symbols used

	Radiographic control
	Collimator light
	Compression force (regulation)
	Compression force (display)
	Tube head rotation keys for stereotactic movement
	Tube head rotation keys (at the top)
	C-Arm angle display
	Vertical movement keys
	Compression thickness display
	Filter selection button
	Tube park keys
	The unit is CE-marked (if the unit contains CE mark) according to the Medical Device Directive 93/42/EEC.
	AEC-mode selection key

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	Earth (ground)
	Protective earth (ground)
	Type B equipment
	Dangerous voltage
	ON (Power)
	OFF (Power)
	Attention, physical danger possible. Refer to Chapter 1.2 and Ch 5 for issues related to radiation, C-Arm rotation and compression.
	Unit (if the unit contains UL/CSA mark) is tested and certified according to UL/CSA (file E218408).
	This symbol (if marked) indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

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